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UNITED STATES
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COMMITTEE ON THE BUDGET

October 15, 2004

The Honorable Tommy Thompson
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Mr. Secretary:

I am writing to you today about the crisis in delivery of flu vaccine. As I travel through my district, my constituents are asking me how we arrived in this situation where the United States is actually rationing access to a critical vaccine? They understand how serious this disease can be, especially since approximately 36,000 people die every year in the United States, and Director Gerberding of the Centers for Disease Control and Prevention (CDC) has said that we can expect that number to increase to some extent due to the shortfall of vaccines.

And I understand that experts believe it is only a matter of time until we have influenza pandemic – something like happened worldwide in 1917. A terrible strain of flu would require much better planning and vaccines that would need to be prepared in a short time. We seem unprepared for that also.

Since the news surfaced on October 5th, we have seen conflicting reports about how this happened. The British say the Food and Drug Administration (FDA) knew what would happen to the Chiron plant in Liverpool, but the FDA says it was not informed of the problem's seriousness. Chiron appeared before the Congress the week before the close of its plant to tell us that all was well and the vaccines would be coming. Clearly there was a serious breakdown in the system, and we need to know exactly what happened and what can be done to prevent it from happening again.

I urge you to begin an investigation by the Department's Inspector General so the American people have an explanation of what went wrong, what actions are being taken to mitigate the shortage of the vaccine, how you plan to ensure that this will never happen again, and your recommendations for the long-range solution of vaccine development, production and delivery for flu and other diseases requiring biologics.

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The Administration has had almost four years to develop solutions to a pandemic flu possibility, and to manage our yearly flu outbreaks, but it appears that a plan and a solution are not close. FDA has made many statements about its suspicions about products manufactured in or re-imported from Western Europe or Canada, yet in this instance, in which the U.S. is dependent on an outsourced plant bought by Chiron, the reverse seems to be true. According to media reports, the British regulatory system took action, but FDA did not inspect Chiron enough to predict the shutdown by the British regulatory authorities. An absolutely critical product was produced off-shore with inadequate oversight by the U.S. authorities, leaving American seniors and children vulnerable to a flu outbreak, and the rest of the population to suffer work loss and illness.

I will look for your prompt response.

Sincerely,

Rosa L. DeLauro
Member of Congress