

Statement of Senator Larry Craig
Liability, Licensing and the Flu Vaccine Market:
Making Decisions Today to Prevent a Crisis Tomorrow
November 16, 2004

Good afternoon and welcome. On September 28th, this committee held a hearing entitled *"Combating the Flu: Keeping Seniors Alive"*. The hearing stressed the seriousness of the disease and the importance of flu vaccine. With 36,000 deaths last year, we cannot underestimate the danger influenza poses to seniors and at risk populations. At that hearing, we were told we could expect to have more flu vaccine this year than ever before. Unfortunately, those expectations changed dramatically a week later when Chiron announced they would be unable to provide the 48 million doses of vaccine they had anticipated.

This announcement dealt a strong blow to U.S. preparedness for this year's season. Chiron's alarming situation is a wake-up call that better long-term flu preparedness is imperative. As we heard at September's hearing, this is especially true in light of the fact that scientists now believe that a return of an especially strong pandemic strain of flu is overdue.

Since October, we have seen outstanding efforts of public health officials, manufacturers, private providers, retailers and all those who have worked so hard to minimize the effects of this year's shortage. I would like to congratulate the countless individuals who took immediate action to be sure that the most vulnerable in our country get the vaccine they need. Today we will hear an update from the CDC and FDA on continuing efforts to that end.

Just as important as the swift reaction to this year's shortage, is the challenge to make quick decisions to avoid this same problem next year and the years after. We have absolutely no time to waste in addressing this issue and making the necessary changes to assure an adequate supply of vaccine in the future. But many questions have yet to be answered. That is why I have decided to hold this hearing now, in November. Flu manufacturers are now making decisions in order to fill orders for next year. We can't wait until Congress is in full swing in February to address next year's supply challenges. By then it will be too late, especially if Chiron Corporation is unable to start production next year. Flu is a worldwide killer and the need for vaccine is clear – and yet, the market has dwindled to the point that the pullout of just one company can devastate our supply.

The reasons for this dilemma are many. Today's hearing is not about pointing fingers and laying blame. This is about looking at the current situation and gathering the information necessary to make needed policy decisions that will address the flu vaccine problem in 2005 and beyond. In conversations with vaccine manufacturers, health officials and other stakeholders, three main areas of concern come up again and again: liability, licensure and the stability of the vaccine market. This afternoon, we will hear from experts that will speak to each of these issues.

Senator Evan Bayh and I introduced legislation earlier this year to further address some of the longer-term issues. For example, our legislation, S. 2038, would encourage an increase in vaccine production capacity by offering a tax credit for companies to invest in the construction or renovation of production facilities. I remain hopeful that the Senate will pass our legislation before we close this session of Congress.

Thank you all for taking time to participate in this hearing today. Before closing, I would like to comment that I found it very disturbing that my staff and I had a difficult time finding appropriate witnesses to speak to these subjects. The combination of liability concerns and reluctance to openly question the regulatory review and approval process have acted to deter participation in this and other hearings on this topic. It's a shame that we have come to the point where people are hesitant to participate in the process.

Thank you all for being here. I have great hope that today's discussion will be of help to lawmakers as we move forward to address this issue.