

# United States Senate

WASHINGTON, DC 20510

October 26, 2004

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

Dear Secretary Thompson,

Influenza results in approximately 36,000 American deaths per year. The increasing recognition of the harm that flu causes has resulted in a rise in vaccination rates among members of high risk groups. The announcement on October 5 that the Chiron Corporation would be unable to supply influenza vaccine for the 2004-2005 flu season threatens this progress and the lives of many Americans. With approximately half the anticipated vaccine supply now unavailable, it is apparent that we will simply not have sufficient supplies of vaccine. We urge you to act immediately to optimize utilization of the available vaccine, and to work to increase the available supply.

**It is essential that use of the remaining influenza vaccine be optimized to achieve greatest effectiveness.** Now that a shortage is evident, the 33 million doses of vaccine already distributed should be targeted, as much as possible, to high risk populations. We also urge the CDC to consider each state's unique needs in allocating new shipments of vaccine. Some orders from Chiron were intended predominately for high risk groups. A one size fits all policy of allocating states only about half their original Chiron order will not provide adequate vaccine to meet the needs of those specified under the CDC Interim Vaccine Recommendations.

**A CDC "clearinghouse" would allow providers to quickly and effectively report their vaccine needs or excess inventory.** For two weeks following announcement of the Chiron license suspension, providers have been referred to county health departments. Such departments do not exist in some states, and when they do, they may be facing state-wide vaccine shortages and have no ability to allocate supply to comply with the new recommendations of the CDC. This jeopardizes the effective distribution of 33 million doses of vaccine which Aventis Pasteur has already shipped. CDC could provide a simple facility to gather this information, so that those either needing supplies or with excess could report via telephone or website. Such a system would facilitate the timely matching of supplies originally intended for lower risk individuals with those with critical needs. We urge the Secretary to immediately address this need.

**Vaccination using a reduced dose may provide effective protection.** Clinical studies have reported effective immunity to influenza has been achieved using as little as 1/10 of the usual dose. Some have suggested that a 50% dose could be utilized for most of the individuals in the CDC recommendations except some infirm individuals, such as seniors in nursing homes. Use of a reduced dose would substantially mitigate the shortage of vaccine. As immunity to flu is induced within 3-4 weeks of vaccination, we request information on any additional studies underway on reduced dose immunization, and request the Secretary consider expedited approval of a reduced dose immunization protocol.

**We must encourage more producers to supply product, and increase the available inventory of vaccine.** We recognize the significant problems to manufacturers of vaccines and these must be addressed by the next Congress. However, as ID Biomedical of Canada has projected that it could supply 10 to 15 million doses of flu vaccine next year, FDA should consider its application expeditiously to begin the process of expanding and diversifying our vaccine supply before next year.

There are obviously many factors that will affect this flu season – such as the strain of the influenza virus we encounter this year, how effective the vaccine protects against it, and how well we practice sound public health measures to prevent its spread. We must not end this year regretting we have not used our vaccine prudently – too many lives are at stake.

We appreciate your consideration and look forward to working with you to ensure that we are doing all we can to protect the health of our citizen this influenza season.

Sincerely,



JACK REED  
United States Senator



SUSAN M. COLLINS  
United States Senator