

Congress of the United States

Washington, DC 20515

October 7, 2004

Secretary Tommy Thompson
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Thompson:

Last influenza season, millions of Americans were forced to risk their health and well being because of a preventable vaccine shortage. This was unfortunate. However, what is even more alarming is that the Government's inaction has allowed history to repeat itself and our most vulnerable populations will be left unprotected once again. The Government has taken few steps forward in preparing our nation to combat the flu and address the 36,000 preventable deaths that occur annually.

This year, we introduced the Flu Protection Act, which was designed to address the influenza vaccine shortage in a comprehensive manner and break the vaccine shortage and delay cycles we have been experiencing for four out of the last six years. Unfortunately, some of the key recommendations in the Flu Protection Act went ignored and people are again left waiting in long lines with little hope of receiving the vaccine and protecting their loved one from a potentially deadly disease.

The recent initiative unveiled by the Centers for Disease Control to purchase and stockpile four and a half million doses of the influenza vaccine acknowledged that the government needs to play a role in ensuring a sufficient supply of the vaccine. This realization is commendable. However, much more needed to be done to make sure that all vulnerable populations were protected against influenza.

Under our proposed Flu Protection Act, the government would work with the CDC and vaccine manufacturers to estimate how many flu vaccines will be purchased each year. Currently there is an economic disincentive for manufacturers to produce an ample supply since each unused vaccine is a direct financial loss for their company. Understanding this dynamic, the federal government should create a guarantee-purchase supply program for the amount of vaccines necessary for each given flu season while educating the public on the need to be vaccinated. The guarantee-purchase supply program would only go into effect if the vaccine doses requested to be produced were not utilized by the end of the flu season by the marketplace. This method would provide manufacturers with an incentive to produce enough vaccines while only spending federal funds if the public becomes complacent and does not get vaccinated and would be a more fiscally responsible approach to current vaccine shortfall.

The Flu Protection Act also calls for greater flu education and outreach, a factor that is crucial in making sure that the Americans who most need the flu shot are prepared to get one. In addition, if the public is properly educated on the need for the vaccine, who should obtain the

vaccine and when to be vaccinated, it is unlikely there will be a large quantity of unused doses at the end of each flu season for the government to consume.

As we have seen this year, we must also do more to decrease our reliance on only two vaccine manufacturers. The Flu Protection Act would have encouraged additional vaccine production in the United States by providing vaccine manufacturers incentives to either build or expand their manufacturing facilities in the U.S. Increasing the number of providers of the flu vaccine will increase our chances for having ample vaccine supply.

In addition to these efforts, we need to make efforts to research alternative influenza vaccines with a faster production time and explore ways to improve upon current vaccine manufacturing methods so that the necessary amount of vaccine is available at the beginning of the flu season when people could use it the most. The Flu Protection Act provides \$100 million a year for such research efforts.

Finally, in the event of a shortage or a pandemic, the Government needs to develop a protocol to disseminate the vaccine to those who need it the most in an emergency and determine which strains to include in the vaccine with greater certainty. The Flu Protection Act would have required such a plan. In August of this year, the CDC indicated that approximately 2 million of Chiron's influenza vaccine doses would be unavailable for shipment due to contamination and that ongoing investigations would determine if their remaining supply would be released. During this time, the CDC should have developed a contingency plan and prepared public health officials in the event that the remaining 48 million of Chiron's doses were unusable. Instead, we find ourselves in the midst of another flu vaccine crisis and with no plan in place.

To address this immediate shortage, we recommend the Centers for Disease Control to quickly review any unreleased vaccine lots to determine if they can be used for this year's flu season, prioritize those who need to be vaccinated through the shot first and determine recommendations for those who can be vaccinated through the FluMist. In addition, the government should take appropriate steps to ensure price gauging does not result as it has in the past during shortages, look for additional vaccine supply domestically and abroad and explore all other methods to manage the complications from the flu such as the use and availability of antivirals.

We have no appropriate excuse to offer Americans with children or older parents who find themselves waiting in line again for flu shots. If our Flu Protection Act had been implemented last year, we would have been a year ahead of where we are today. We cannot afford any additional delays and urge you to support the Flu Protection Act.

Sincerely,



Evan Bayh



Rahm Emanuel