The U.S. Senate’s Homeland Security and Governmental Affairs Committee held a hearing to determine why vaccine for pandemic influenza A(H1N1) virus is taking so long to reach the 159 million Americans in the designated high-risk groups. As of Nov. 23, 34% of the vaccine needed for the initial target groups was available.

In a letter to Health and Human Services Secretary Kathleen Sebelius, Sen. Joe Lieberman (I-Conn.), who chairs the committee, together with ranking minority member Sen. Susan M. Collins (R-Maine), criticized the HHS’s decision to designate nearly half the U.S. population in one of the high-risk groups.

“I share your disappointment in the initial production and the supply constraints that we have today,” Dr. Anne Schuchat said in her opening statement at the hearing. Dr. Schuchat is director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention. “We have all been victim to the biologic processes of a slow-growing virus, and it really underscores the needs for those long-term investments in the technology and the production capacity. But production is accelerating and substantial amounts are becoming available.”

The committee’s letter to Secretary Sebelius pointed out that an HHS advisory committee had prepared a contingency plan for an extreme vaccine shortage. According to that plan, vaccine would have been reserved for the 42 million Americans at greatest risk. But that plan was never implemented.

Instead the federal government gave state and local governments the discretion to decide how to distribute vaccine. “People rightly do not understand why in their area they are not eligible to get vaccinated, while individuals in a similar risk category across the state or city line are told they can get the vaccine,” the letter reads.

“We have been supporting state and local decision making on the best ways to put vaccine in the path of the priority populations,” Dr. Schuchat said.

“We know that states are carrying this out in a variety of ways. Thirty-four states so far have initiated school-located vaccine efforts. Virtually all of the states are providing vaccines to providers. Some are using lotteries to decide who gets the vaccine. Some have ethics boards. Some are focusing on high-risk providers that serve the highest-risk children or adults,” she explained.

And Dr. Schuchat noted that if the vaccine had been reserved for only the 42 million Americans at highest risk, millions of healthy school-age children would have been left out.

She said that “reasonable experts” disagreed on whether that tighter targeting would be desirable.

“I do believe that we need a thorough evaluation of the preparedness at the state and local level,” Sen. Collins said at the hearing. “It does vary enormously, because some states devote a lot of resources and some states don’t. Some states are making good decisions and some states aren’t. And that applies to big city health departments as well.

“We are not waiting for states or cities to fail,” Dr. Schuchat replied. “We are working very actively, monitoring the ordering, understanding what’s going on, offering assistance, and working on some of the missteps that we believe may be happening in some areas.”

At the hearing, Dr. Nicole Lurie, who is assistant secretary for preparedness and response at HHS, detailed some of the causes for the shortage. For example, while the remnants of Hurricane Ida were still menacing the Gulf Coast, some of the manufacturers’ insurance carriers insisted that vaccine deliveries be delayed.

Sen. Collins focused on two other possible explanations for the shortfall: the reliance on prefilled single-use syringes and the failure to incorporate adjuvants into the vaccine formulations. Adjuvants, which are being used in H1N1 vaccines distributed in other countries, help the immune system mount a larger response to a smaller amount of vaccine, thus stretching the supply.

Dr. Lurie said that the U.S. government contracted for a mixed supply of prefilled syringes and multi-use vials. And when it became evident that there would be a shortage, the manufacturers were instructed to focus on filling the multi-use vials. Only when they had more vaccine than they could handle on those assembly lines would they start producing prefilled syringes. The bottom line is that the issue of vials versus syringes turned out not to have an appreciable effect on the supply, Dr. Lurie said.

The adjuvant story was somewhat more complex. Dr. Lurie said that experts reviewed the decision not to use adjuvants several times, but each time they decided against changing course.

There were two main reasons, Dr. Lurie said. First, the decision to add adjuvants would have delayed vaccine production capacity. “All the figures illustrating the extent of the pandemic in the United States. So far 22 million Americans have been infected with H1N1 influenza, resulting in 98,000 hospitalizations and more than 3,900 deaths. These figures are substantially higher than those that were previously released because the CDC is no longer requiring laboratory confirmation that individual cases of influenza-like illness be confirmed as H1N1 infection before being counted.

Data Suggest Seasonal Flu Vaccine May Mitigate H1N1

**BY HEIDI SPLETE**

**WASHINGTON** The 2008 seasonal flu vaccine showed an overall vaccine effectiveness of 45% against infection with the pandemic influenza A/H1N1 virus in a study of military personnel conducted between April and October 2009, according to findings presented at the annual meeting of the American Society of Tropical Medicine and Hygiene.

This rate of vaccine effectiveness means that those vaccinated have a 45% lower chance of developing influenza A(H1N1). (Dr. Sanchez noted that the contribution of natural influenza infections and prior influenza immunizations may contribute to “immunological priming” and create a cross-protective effect in active-duty military settings.)

But he emphasized the importance of seasonal flu vaccination, even with the flood of attention being given to the H1N1 influenza virus. In an interview, he encouraged physicians not to forget about the seasonal flu vaccine, and to remind their patients to get vaccinated.

The military is in a unique position to monitor vaccine effectiveness in young and middle-aged adults, including groups of at-risk individuals that can be studied in randomized clinical trials, and data collection is ongoing, said Dr. Sanchez. The results may help guide both seasonal and H1N1 vaccination in the military and Department of Defense dependents, he added.

Dr. Sanchez had no financial conflicts to disclose.