

Will Vaccine Funds Be In Time for Pandemic?

by Christine Craig and Laurence Hecht

By a vote of 94-3, the Senate passed an \$8 billion appropriation, initiated by Sen. Tom Harkin (D-Iowa), to fight the threatening avian flu pandemic. The measure, passed Oct. 27, must still go before the House. The funding came as an amendment to the Labor, Health and Human Services, and Education Appropriations bill for 2006, and apparently subsumed funding (mostly for anti-viral drugs) from a previous amendment to the Defense Appropriations bill.

The amendment provides:

- \$3.3 billion for vaccine development;
- \$3.1 billion for the stockpile of anti-viral drugs;
- \$600 million for state and local public health agencies;
- \$750 million to manage possible patient surge on hospitals during a pandemic; and
- \$185 million for the Centers for Disease Control (CDC) to handle an outbreak.

A few days earlier, on Oct. 25, Secretary of Health and Human Services Michael Leavitt, just returned from a fact-finding tour of Southeast Asia, was in Ottawa, Canada, representing the United States at an international conference on pandemic preparedness for the avian flu. Health ministers from 30 countries and several international organizations had gathered there to prioritize responses to the looming threat of a devastating pandemic.

These actions by the government signal a growing recognition of the seriousness of the situation with respect to the avian flu.

That's the good news. The bad news is it may be nowhere near enough. The H5N1 avian flu virus has killed more than half of the 121 people so far infected. Virologists believe that it is only a matter of time before the virus will mutate or reassort into a form that will be easily transmissible from human to human. Once that happens, if the virus retains its present fatality rate, a pandemic worse than the 1918 flu epidemic which wiped out 50 million people in less than a year, will ensue. No one can predict when such a change will occur, but it could be as early as this flu season. Compounding the problem, is the fact that the deadly strain of the flu has re-infected the migratory bird population, which has recently been migrating south to over-winter. Recent outbreaks of avian flu in domestic poultry in Romania, Turkey, and Croatia seem to have spread via the wild birds. Each new infection of

an animal or person increases the possibility of a mutation to a strain that is easily transmissible from human to human.

Knowing that, governments must mobilize on a scale never-before-seen to protect populations. Some experts have called for a “Manhattan Project” type of mobilization. The measures proposed to the Senate are a beginning, but the amounts of monies needed would have to be 10 or 100 times larger to carry out a serious global preventive program. Among the needed immediate measures are a vast gear-up in vaccine and anti-viral production capability; expansion of public health services and monitoring agencies; preparation of hospitals and emergency overflow facilities such as at military bases; and other emergency preparedness of all types.

Immediate assistance to the frontline states in southeast Asia could make the crucial difference in whether, and when, the H5N1 virus mutates to a human-transmissible form. This was emphasized at the Ottawa conference by representatives from the Food and Agriculture Organization (FAO) and the World Organization for Animal health (OIE). Jacques Diouf, director-general of the FAO, commented that the disease is still, at this point, an animal disease, which has caused economic devastation throughout Southeast Asia, and increasingly, in Europe. One focus of international efforts should be toward stamping out the disease at its source—the poultry flocks of Southeast Asia. The disease has already cost the region over \$10 billion; and economic losses could rise to hundreds of billions if the animal pandemic is not stamped out soon. This theme was echoed by Alejandro Thiermann of the World Organization of Animal Health, who told delegates, “Our first line of defense should be attacking the problem at the poultry level.”

Diouf chastised countries for their reluctance to fund the FAO in their efforts to fight the avian flu in Southeast Asian poultry flocks. According to him, months ago the FAO had set up a \$175 million fund to begin the work of bringing the bird flu under control in Asia. Of a paltry \$30 million pledged by countries so far, not a cent had been received. He estimated at least a billion dollars would be needed to supply, and man the effort in Asia.

A Preparedness Strategy

Secretary Leavitt expressed some pessimism over the ability of Asian countries to get a handle on their poultry pandemic, at a National Press Club luncheon on Oct. 27. He mentioned a certain Asian country in which 14,000 people had died of rabies last year. How then to rally an effort over some dead birds, when they didn’t have the infrastructure to deal with a well-characterized and completely treatable human disease? This story led him into his take-home message: We had better prepare at home. Leavitt gave the National Press Club audience a preview of the Administration’s soon-to-be-released National Strategy for Pandemic Preparedness. Here are some of the points he emphasized:

- Improve national and international surveillance of

the virus.

- Stockpile anti-virals and vaccines.
- Create a seamless network of health-care and other emergency responders, both private and public.
- Expand biological information technology capabilities.
- Improve public communication and education to spur citizens into action without panicking them.

Both Senator Harkin and Secretary Leavitt have recently stressed the primary importance of adequate vaccine capability in fighting avian flu. Only one company, Sanofi-Pasteur, now produces flu vaccine in the United States. Its capacity is limited to 60 million doses per year. The National Institutes of Health (NIH) and Sanofi-Pasteur have recently developed a vaccine based on the H5N1 strain, which has shown promise in clinical trials. According to Leavitt, we already have a \$100 million contract with Sanofi-Pasteur to produce 3.3 million doses of the H5N1 vaccine. The United States has also awarded \$62.5 million to Chiron for new vaccine development. Both Harkin and Leavitt stressed the necessity to immediately revive vaccine production capabilities, and to develop the new cell-based vaccine production technology to replace the archaic egg-based system now used to produce normal flu vaccines. Harkin stressed the importance of rapidly building new vaccine production plants, commenting that the Pentagon was built in merely nine months. The normal time from plans to production is usually closer to five years. He expressed a readiness on the part of government to subsidize industry to facilitate development, either with up-front money or by guaranteed buy-up of vaccine.

In contrast to the usual approach of the Bush Administration, Leavitt closed his briefing at the Press Club with some interesting comments actually touching on the general welfare and the concept of the science driver. He posed the question: What if the H5N1 never jumps to humans, never materializes as a human pandemic. Will we be held accountable for having guessed wrong and acted? He insisted that the effort would in no way be wasted, that science and history teach us that what we do now will have lasting value. The increased preparedness, the revitalized industry, and the new technology will change the world forever. There will be serious long-term benefit from our short-term planning, and whenever a pandemic does come along, we will be ready.

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