Building a Safety Nest for Avian Flu: Government Moving Slowly on Twig Collection

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If avian influenza hits America, no one will be able to accuse U.S. officials of doing nothing to prepare for the pandemic. This time, there is less likely to be a repeat of the finger-pointing at the Federal Emergency Management Agency (FEMA) and the Bush administration that characterized the post-Hurricane Katrina stories.

However, it is not clear that the preparation by the Department of Health and Human Services (DHHS) and the Centers for Disease Control and Prevention (CDC) has been sufficient. Certainly, the DHHS should have published an emergency response plan by sooner than it did. In August 2004, the agency published a draft called Pandemic Influenza Response and Preparedness Plan. That was the last anyone heard of it, until November 2, when details of the plan were released—over a year later.

Last May, Marcia Crosse, director of health care issues for the U.S. Government Accountability Office (GAO), told a House committee that the draft plan does not address certain critical issues, including how vaccine for an influenza pandemic will be purchased, distributed, and administered; how population groups will be prioritized for vaccination; what quarantine authorities or travel restrictions may need to be invoked; and how federal resources should be deployed.

That is why Senate Democrats, under the leadership of Minority Leader Harry Reid (D-Nev.), introduced the Pandemic Preparedness and Response Act (S. 1821) on October 5. Although the bill is not aimed exclusively at avian flu, it establishes a position of Flu Czar at the White House and requires the government to stockpile enough antiviral medication for 50% of the population. It is unfortunate that no Republicans cosponsored the bill or were even interested in it, according to Reid spokeswoman Rebecca Kirszner. This does not bode well for the bill’s legislative progress.

With regard to the H5N1 avian influenza virus now percolating in Asia (it has apparently jumped to Turkey and Britain of late), the U.S. is far short of its 50% goal. Until now, the nation’s drug stockpile contains approximately 2.3 million courses of treatment of Hoffmann-LaRoche’s Tamiflu®, the only antiviral agent known to be effective against the current strain of H5N1. Roche has received a nonbinding letter of intent from the DHHS to purchase an additional three million courses of treatment. In contrast, countries such as the United Kingdom, France, Finland, Norway, Switzerland, and New Zealand are ordering enough Tamiflu® to cover between 20% and 40% of their populations, says Dominick Iacuzio, Roche’s medical director.

The DHHS just awarded a $100 million contract to sanofi pasteur to manufacture avian influenza vaccine, but the agency doesn’t have the foggiest idea about how many doses will come of that. sanofi pasteur had previously delivered 8,000 doses of investigational influenza vaccine based on the H5N1 avian influenza virus strain to the National Institutes of Health, which is conducting clinical trials. In September 2004, the company was awarded a contract by DHHS to produce two million bulk doses of an attenuated version of the same H5N1 avian influenza virus strain of vaccine. However, the U.S. would need close to 180 million doses in the case of an outbreak, and there have never been more than 85 million doses available for all vaccines in a given year.

The DHHS apparently realized that the sanofi contract was insufficient. That is why it awarded a second contract worth $62.5 million to Chiron Corporation at the end of October, also for the manufacture of an avian influenza vaccine designed to protect against the H5N1 influenza. Mike Levitt, DHHS Secretary, said that this purchase “builds on the department’s plan to buy enough H5N1 vaccine for 20 million people and enough influenza antivirals for another 20 million people.”

Of course, vaccines and antivirals have the same potential chink in their armor: the inability to work against a mutated H5N1 virus. Nobody can predict whether that same virus would develop decreased sensitivity to Tamiflu®. Even if Roche started a sweeping manufacturing program the moment the H5N1 virus arrived on these shores, there is no guarantee that the virus, once here, would not mutate, making all that Tamiflu® useless. However, while the H5N1 virus could mutate or develop resistance to a vaccine or an antiviral by the time it hits—if it hits—U.S. shores, antivirals do have some advantages. They might make more sense than vaccines for a number of reasons, it seems; they can be stockpiled for years (vaccines have to be made annually), they work immediately after they are administered, and they work against multiple types of influenza.

At this point, however, neither sanofi nor Roche—or any other antiviral or vaccine producer—is likely to start manufacturing tens of millions of doses of anything until they get congressional assurance, via legislation, that they will not be liable for any unintended medical ramifications stemming from mass dosings.