

## **Protein Sciences enlisting help of U.S. Congress officials in seeking funding**

*By Mary Ellen Godin, Record-Journal business editor*

MERIDEN — Just days after President Bush announced a \$7.1 billion plan to protect U.S. citizens against a possible bird flu pandemic, one local vaccine maker has some hard questions about the rationale.

Why is the U.S. government putting the big money into time-consuming, outdated egg-based technology? Why isn't it helping companies with tested cleaner vaccines produce them faster?

Protein Sciences Corp., which last month received a temporary Food and Drug Administration license for its cell-based FluBlok influenza vaccine, has been testing its H5N1 avian flu immunization in animals with promising results, said Manon Cox, chief operating officer.

Cox said the vaccine is 100 percent effective in killing the virus. With the FDA's recent approval for FluBlok, the company is now better equipped to find a manufacturing partner.

Protein Sciences is in talks with two out-of-state and one overseas manufacturer about teaming up to manufacture FluBlok. If the U.S. government isn't interested in Protein Science's work with the H5NI, or bird flu, the company will make it available to other countries, Cox said. The results of studies in animal tests have the FDA putting it on a fast track toward licensure.

But the FDA doesn't dole out the funding.

"If Mr. Bush wants to wait for 2009 for Sanofi," Protein Sciences can deliver it faster to other countries, she said.

According to Cox, the Research Parkway bio-science research company was told by the federal government last summer that it had a good chance of receiving funding to continue testing and to manufacture doses to fight H5NI in humans. But in October, the Department of Health and Human Services rejected the funding request.

Department officials did not return a request for comment for this story, but an agency official recently stated the department had concerns about the number of staff members and Protein Science's manufacturing capability.

In April, the department announced a \$97 million, five-year contract to Sanofi Pasteur to develop a cell-based vaccine and build a cell-based manufacturing structure capable of producing 300 million doses of vaccine. Sanofi Pasteur is already a large supplier of egg-based vaccine with an egg incubation facility in Pennsylvania. It does not have a cell-based vaccine.

However, in September, the department granted Sanofi another \$100 million to make egg-based vaccines against H5N1 avian flu and build up egg production to help the nation's stockpile. The company is expected to produce 20 million doses.

"This is no longer about science, this is politics. There is a lot of lobbying going on," Cox said. "We are in a much stronger position."

Protein Sciences has taken its case to U.S. Rep. Nancy L. Johnson, R-5th, the chairwoman of the House health subcommittee.

Johnson visited Protein Sciences in August and saw its research capabilities first hand, said her spokesman, Brian Schubert. She's also had several high-level discussions with DHHS on the company's behalf.

According to Schubert, the department has informed Johnson the case is under independent review. Johnson is awaiting a final report.

"We must take every possible step to prepare for an avian flu pandemic," Johnson stated via e-mail. "Protein Sciences is getting mixed signals from the federal government, and that needs to be resolved. I want to make sure its research proposal is not lost in a bureaucratic black hole."

But Cox isn't waiting and is proving the company can play politics as well as federal agencies. She said company President and Chief Executive Officer Daniel Adams has brought the matter to the attention of U.S. Sen. Edward Kennedy D-Mass., a ranking member

of the Senate Committee on Health, Education, Labor and Pensions. Cox hopes pressure from both parties and both houses of Congress will help Protein Science's case.

She is also continuing her talks with three potential manufacturing partners. One manufacturer has a 10,000-liter capacity that can produce 9 million doses every week of a pandemic, she said. Another manufacturer can double that amount. She would not identify the manufacturers, except to say one is overseas and the other two are outside of Connecticut.

Last year, Protein Sciences came before the city's Planning Commission and won approval to build its own manufacturing plant on Research Parkway. According to Cox, the company couldn't get the financial backing to move forward. Unlike the pharmaceutical market, vaccine production isn't a big moneymaker.

"Nobody wants to invest in steel," Cox said. "This is going to be interesting."

[mgodin@record-journal.com](mailto:mgodin@record-journal.com)

(203) 317-2455