

## **Protein Sciences is in Phase III of new kind of shot**

*By Mary Ellen Godin, Record-Journal staff*

MERIDEN —Using egg-based methods to make flu shots is at the heart of the alarming vaccine shortage this season, said the president of a flu-shot manufacturing firm on Research Parkway.

Protein Sciences is beginning Phase III trials of its flu shot using insect cell-based technology and claims the method is cleaner, more effective, reliable and takes less time to manufacture, said President and Chief Executive Officer Daniel Adams.

For that reason, the federal government has intensified negotiations with the company, but Adams could not elaborate on what is being discussed.

The company's vaccine called FluBLOK successfully completed two tests in healthy adults and is expected to be tested for a third time this winter before applying to the federal Food and Drug Administration for licensing. It was projected to be on the market in 2007.

"But all that could change," said Adams. "We're getting attention. We've been told that everybody is seeing to getting this finished."

The federal Health and Human Services Department announced Tuesday that one of two egg-based influenza manufacturers and providers of all influenza vaccines for the world had contaminated vaccines which cut in half the total 48 million doses expected for the upcoming flu season.

Adams was in the conference audience when the announcement was made and when the government announced it would step up its efforts to provide more incentives to alternative manufacturers.

"If something goes wrong, like now, late in the process, it becomes very, very difficult to re-gear up the process of growing the virus in

question in the eggs and processing it to the point of making it a vaccine," said Tony Fauci, director of the National Institute of Allergy and Infectious Diseases, part of the National Institute of Health.

Fauci said that one of the NIAID's priorities is to ensure that the industry doesn't have to depend upon the long cyclic type of preparation of "chickens to eggs, eggs to virus, virus to vaccine and that is gradually transitioned with the cell-based development of vaccine for virus."

"It gives you much more direct control," Fauci said. "And we are funding research into trying to perfect better the cell culture-based approach toward the development of the vaccine."

The government is also reviewing what it can do to offer more incentives to manufacturers to make vaccines.

Studies have shown that companies might be shunning vaccine manufacturing because they could make more money on other products.

Protein Sciences was only one of three vaccine makers, and the smallest, to receive a federal grant to begin the studies two years ago. Needless to say, its results are closely watched.

Adams has long called the egg process primitive and explained that the contamination problems stem from the chemicals used to sterilize the egg viruses. In the most recent case, the culprit was a mercury derivative.

"We don't have to adapt the virus, so we're going to be exactly right 50 percent of the time," Adams said, adding that's a far greater ratio than egg-based methods.

Insect cells don't harbor human viruses, so they don't need to use harmful preservatives to kill them. He also said that egg-based vaccines are not as effective as cell-based.

"It doesn't protect the elderly well, maybe 30 to 50 percent," he said. "Ours is 96 percent."

Final testing is ongoing at the Vaccine Treatment and Evaluation Units at the University of Rochester, Baylor College of Medicine and the Cincinnati Children's Hospital Medical Center.

"It's going to be easy to recruit," Adams said of the upcoming field trial.

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