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Partnerships touted for work with vaccines

Del.'s biotechnology industry showcased at conference

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As researchers turn to plants, insects, stem cells and other building blocks to produce new vaccines, partnerships will be critical in pushing the technologies to market.

The effort got a boost last week during a four-day conference in Wilmington. The meeting, titled "New Cells for New Vaccines III: From Lab Bench to Clinical Trials," brought together about 140 attendees from 10 countries at the Hotel du Pont last Sunday through Wednesday.

The conference included representatives from universities, governments, foundations, non-governmental organizations, independent research labs and the pharmaceutical and biotechnology industries.

Conference participants said each sector has a role to play as researchers look beyond the traditional method of vaccine development -- growing a virus in chicken eggs -- to find new solutions for pandemic flu, malaria, HIV and a host of other global public health challenges.

"There is no organization on this planet, no government, that can take care of this problem on its own," Douglas Holtzman, senior program officer for the Bill & Melinda Gates Foundation, said during a presentation Tuesday morning.

The vaccine conference was organized and sponsored by two Newark companies -- Fraunhofer Center for Molecular Biotechnology, a nonprofit research group, and iBioPharma Inc., a company developing vaccine candidates using a plant-based technology purchased from Fraunhofer. The Delaware Economic Development Office also was a sponsor.

Vidadi Yusibov, executive director of Fraunhofer, said the conference was helpful in exposing Delaware's biotechnology industry to a wider audience. This was the event's third year, and its second in Wilmington.

Fraunhofer collaborates on vaccine-related projects with universities, foundations and governments around the world. For example, Holtzman detailed one of the Gates Foundation's projects, an effort to develop a vaccine for African trypanosomiasis -- also known as sleeping sickness -- in cattle. In addition to Fraunhofer, the project included collaborators from Makerere University in Uganda and McGill University in Montreal.

The Seattle-based foundation, started by the Microsoft founder and his wife, has a goal of preventing 4 million deaths a year by increasing the use of existing vaccines and introducing new ones. The foundation has donated nearly \$2 billion since 1998 to vaccine development efforts.

"Meetings like this are very fertile ground for identifying collaborators and innovations," Holtzman said on the sidelines of the conference.



Ornkleaw Zepp, a research assistant at Fraunhofer Center for Molecular Biotechnology, rinses plants that have gone through a process called vacuum infiltration that places bacteria into the plants.



Plants containing a target protein are harvested and ground up to extract it. The material is purified to be used in producing a vaccine.

Yusibov said the global network of companies, governments, universities and foundations involved in vaccine development illustrates how complex the task is, since the origins of diseases -- and the greatest market opportunities -- are often found in the poorest parts of the world.

"The diseases do not necessarily occur here," Yusibov said. "We need to look at the global picture."

Fraunhofer, aided by a \$5 million grant from the state, is building a 14,000-square-foot pilot-scale production facility to produce material for clinical trials at its home in the Delaware Technology Park.

Fraunhofer's technology works by introducing an antigen -- a substance that provokes a response from the body's immune system -- into a molecular vehicle known as a "launch vector."

The launch vectors, carrying the antigen's genetic code, are introduced into bacteria, where they multiply rapidly. Tobacco plants are then dunked into a solution containing the bacteria, which enter the plants through a process called vacuum infiltration.

Inside the plant, the genetic material multiplies rapidly, producing the target protein. Within a week, the plants are harvested and ground up to extract the protein, which is further purified into material suitable for a vaccine.

iBioPharma, which recently spun off from a parent company and changed its name from InB:Biotechnologies, entered into a deal with Fraunhofer in 2004 to acquire the nonprofit's technology. The six-employee company announced last month that it has chosen a plant-made flu vaccine as its first candidate for clinical development in humans.

Jennifer Kmiec, vice president for business development and marketing for iBioPharma, said the plant-based process offers the potential to produce a large amount of vaccine in a shorter period of time than the traditional method of cultivating vaccines in chicken eggs. Such "surge capacity" could be critical in responding to a flu pandemic.

iBioPharma hopes to submit an investigational new drug application with the U.S. Food and Drug Administration in the second quarter of 2009, a step needed to begin clinical trials in humans. Kmiec said the company would like to get its vaccine through the first of three stages of clinical trials before seeking a larger pharmaceutical or biotechnology company as a development partner.

"The further we can take it, the more value we can offer to a partner," Kmiec said.

For iBioPharma, Kmiec said, the vaccine conference offered a chance to find business development opportunities and get its name out in front of prominent researchers and companies in the vaccine field.

Conference organizers also said the presence of the FDA was crucial as researchers work to produce vaccines using cells not just from plants, but also algae, bacteria, mushrooms and other organisms. For example, Savage, Md.-based Chesapeake PERL, which has a lab in Newark, is working to develop a smallpox vaccine using insect larvae from moths.

Fraunhofer's Yusibov said the industry needs to work hand-in-hand with regulatory agencies to prepare them for new vaccines in development.

"There's this jungle of new technologies coming and we're going to be knocking on your door," Yusibov said. "Are you ready?"



Hassane Elhassani, a lab technician at Fraunhofer Center for Molecular Biology in Newark, checks plants in a recovery room after they were infiltrated with bacteria.