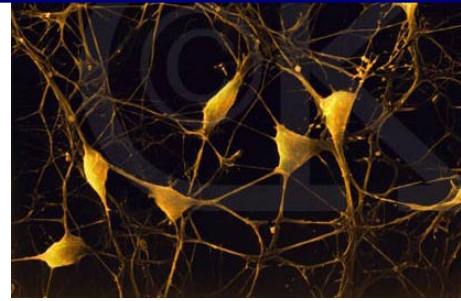




HHS Awards \$487 Million Contract to Build First U.S. Manufacturing Facility for Cell-Based Influenza Vaccine

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The U.S. Department of Health and Human Services (HHS) today announced a \$487 million multiple year contract with Novartis Vaccines and Diagnostics, Inc., to build the first U.S. facility to manufacture cell-based vaccine for seasonal and pandemic flu. Because cell-based influenza vaccine can be made faster and in greater quantities than traditional vaccine, the new facility is expected to increase the U.S. capacity to make pandemic influenza vaccine by at least 25 percent.

HOSA, in partnership with PTA, FluBusters, and Novartis Vaccines, is part of a national initiative, Let's Fight Flu Together! The goal of this initiative is to Educate, Motivate, and Vaccinate.



Cell-based vaccine production could more easily meet surge capacity needs because cells could be frozen and stored in advance of an epidemic or developed rapidly in response to an epidemic. Cell-based vaccine production also dramatically reduces the possibility for contamination and promises to be more reliable, flexible, and expandable than egg-based methods.

Currently, influenza vaccines licensed by the U.S. Food and Drug Administration (FDA) are made in specialized chicken eggs using a process that has changed little in over 50 years. In place of eggs, cell-based vaccine production uses laboratory-grown cells that are capable of hosting a growing virus. The virus is injected into the cells where it multiplies. The cells' outer walls are removed, harvested, purified, and inactivated. Using this technology, a vaccine can be produced in a matter of weeks.

"Today we are taking an important step in our ongoing commitment to pandemic preparedness," said Dr. Robin Robinson, director of the HHS Biomedical Advanced Research and Development Authority (BARDA), which will oversee the contract. "In a pandemic we would

need vaccine ready within six months. That's why the National Strategy for Pandemic Influenza set domestic surge capacity as a goal in preparing the nation for a pandemic. That goal could not be accomplished using the traditional egg-based method of producing flu vaccine."

New cell-based influenza vaccines provides an option for people who are allergic to eggs and, therefore, unable to receive current flu vaccines. Cell-based production avoids other problems that egg-based production has, such as a potential shortage of eggs due to poultry-based diseases.

The cell-based vaccine technology can also be used to make vaccines for seasonal influenza and other major emerging infectious diseases.

Under the contract, Novartis and HHS share the cost of the new cell-based influenza vaccine manufacturing facility in Holly Springs, N.C., with the HHS contract covering 40 percent of the cost and Novartis bearing 60 percent.

Also under the contract, Novartis will provide two new flu vaccines for seasonal flu or for pre-pandemic use. The contract builds on progress made through a previous HHS contract award to Novartis to accelerate the development of cell-based influenza vaccine.

The new contract also will fund scientific studies, called clinical bridging studies, to compare existing Novartis vaccines to new ones, including those developed in the new facility, to show that these new ones are also safe and effective. By comparing new and existing vaccines, the company can provide information quickly to the FDA to request licenses for the new vaccines.

If licensed by the FDA, the new cell-based vaccines made in the United States could be purchased for by the federal government for vaccine stockpiles.