A press release from the U.S. Department of Health and Human Services last Thursday, Jan. 17 contained a statement from Assistant Secretary for Preparedness and Response (ASPR) Nicole Lurie on FDA approval of a new influenza vaccine manufactured with novel technology.

"Our nation has reached a landmark in influenza vaccine history with the U.S. Food and Drug Administration's approval of a new seasonal flu vaccine called Flublok, made with novel technology," said Lurie.

This method uses recombinant DNA and a modified baculovirus (a virus that infects insects) to produce a safe and effective human flu vaccine.

"The approval of the new vaccine produced with this modern technology stands as one of the most significant improvements in flu vaccine technology in the past 50 years," said Lurie.

"I am honored that such a remarkable advancement came through a public-private partnership between ASPR's Biomedical Advanced Research and Development Authority and Protein Sciences Corporation," said Lurie.

Since its inception in 2006, BARDA has worked steadily with private industry to advance influenza vaccine technology and develop flu vaccines with these modern technologies that are FDA approved, ultimately providing more domestic pandemic vaccine capacity.

As part of these national pandemic preparedness efforts, the National Institute of Allergy and Infectious Diseases supported early stage development of this vaccine and in 2009, when the vaccine reached an advanced development stage, BARDA began a partnership with Protein Sciences Corporation to reach the results we are seeing today: a new flu vaccine made with modern technology, explained Lurie.

"Demand for influenza vaccine can increase with little warning in a pandemic and in years when the flu is especially widespread," she said. "The method used to manufacture Flublok may help meet the increased demand for flu vaccine quickly because it has the potential for faster start-up of the manufacturing process than traditional egg-based vaccine methods."

Lurie said the process is nimble enough to be used for seasonal as well as potentially for pandemic flu vaccine because the technology does not depend on an egg supply or on the availability of modified influenza virus for production like traditional egg-based vaccine manufacturing does.

"This new way of making flu vaccine is an example of the Obama administration partnering with industry to move innovative technology forward to the market," said Lurie. "Our goal in ASPR is to drive innovative development of effective and cost-efficient vaccines, drugs, diagnostics, and medical equipment to protect public health during emergencies.

Many of these innovations also hold potential day-to-day uses, as is often the case with seasonal and pandemic flu technology."

BARDA also worked with its partners to achieve FDA approval for the first flu vaccine manufactured using a cell-based technology and, through a public-private partnership, opened the first cell-based flu vaccine manufacturing plant in the United States.

This past year, BARDA engaged private partners around the country in a new way through three Centers for Innovation in Advanced Development and Manufacturing that will support pandemic as well as biodefense readiness.

"This HHS record of progress shows the power of public-private partnership." she said. "By working together –industry, non-government organizations and all levels of government–we can help save lives, improve public health preparedness and potentially increase health security for

our nation. FDA approval of Flublok is an important step toward that goal.”