

# BARDA Signals Support For Recombinant Vaccine Tech, Adjuvants

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The Obama administration's advanced medical countermeasures research arm has signaled its interest in both recombinant vaccines and adjuvants, even though FDA has been hesitant to embrace the technology that could dramatically increase the number of doses of vaccines available in the next pandemic.

HHS' Biomedical Advanced Research and Development Authority awarded last week up to nearly \$400 million to two firms developing recombinant influenza vaccines, which use cell-based cultures as opposed to traditional egg-based methods to manufacture vaccines. Novavax, Inc. received \$97 million for the first three years of the contract, which can be extended for two additional years. VaxInnate, Inc. obtained \$117.9 million for the first three years, with that contract reaching up to \$196.6 million for an additional two years.

"This investment in my view is an endorsement by the policy makers to really move the production technology away from eggs and into cell culture, and into a production technology that can respond faster," Novavax President and CEO Rahul Singhvi told *FDA Week*.

Novavax hopes to make the first lot of its vaccine available 12 weeks after identifying the strain of the influenza virus, which would drastically accelerate U.S. capabilities to vaccinate the population after a pandemic declaration.

The Novavax contract even includes the development and studies of adjuvants, which are products administered either with or as part of a vaccine that enhances patient response, thereby enabling the patient to be administered less of the vaccine to obtain the desired outcome. A company official said the original BARDA solicitation did not include a requirement for adjuvant development, but BARDA requested the company explore these products. Novavax will conduct studies comparing the firm's adjuvant with a vaccine to a non-adjuvanted vaccine and comparing their adjuvant with another yet-to-be-determined adjuvant, the company official said.

FDA has not fully embraced either adjuvant. During the H1N1 influenza crisis, several lawmakers criticized HHS because adjuvants were not available in the United States even though the H1N1 vaccine was in high demand. Industry testified at a House Energy and Commerce Committee hearing that adjuvants could quadruple the vaccine supply, but FDA has not approved any of these products. FDA had not approved an adjuvant based on European data, urging companies to conduct U.S.-based clinical trials, which representatives from firms opposed (see *FDA Week*, Nov. 20, 2009).

At the time, HHS Assistant Secretary for Preparedness and Response Nicole Lurie said public hesitancy to taking vaccines would increase if FDA hastily approved the products. "The public confidence in our vaccine system and in vaccines in our country is very, very fragile and we made a commitment not to cut corners," she said in 2009.

Similarly, FDA has primarily approved egg-based vaccine production methods, as this manufacturing process has been used for decades. But, FDA has licensed for immunization and distribution some cell-based vaccines, such as Gardasil, Merck's Human Papillomavirus Quadrivalent vaccine. Since obtaining the contract, Novavax has received high-profile support. Maryland Governor Martin O'Malley (D) and Rep. Chris Van Hollen (D-MD) toured the Novavax facility Monday (March 7) and lauded the firm for developing life-saving therapies. -- Ben Moscovitch ( [bmoscovitch@iwpnews.com](mailto:bmoscovitch@iwpnews.com) )