



News Release

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FOR IMMEDIATE RELEASE

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HHS creates new centers to develop, manufacture medical countermeasures

Centers are first major U.S. domestic infrastructure to address biodefense threats and pandemic influenza

The U.S. Department of Health and Human Services today established three new centers to develop and manufacture medical countermeasures, such as vaccines and medicines used to protect health in emergencies, and can transition quickly and cost effectively between products. The centers will aid in bringing new medical countermeasures to the market faster and would help to train the biopharmaceutical workforce needed in the future.

“Establishing these centers represents a dramatic step forward in ensuring that the United States can produce life-saving countermeasures quickly and nimbly,” said HHS Secretary Kathleen Sebelius. “They will improve our ability to protect Americans’ health in an emergency and help fill gaps in preparedness so that our nation can respond to known or unknown threats.”

Created as public-private partnerships, the Centers for Innovation in Advanced Development and Manufacturing will provide the first major domestic infrastructure in the United States capable of producing medical countermeasures to protect Americans from the health impacts of bioterrorism as well as pandemic influenza and other epidemics.

In creating the centers, HHS is using a new public-private partnership model, bringing together the innovative ideas of small biotech firms, the training expertise of academic institutions, and the development and manufacturing experience of large pharmaceutical companies.

Each center will be run by a consortium led by an organization experienced in developing or manufacturing medical countermeasures. HHS will invest approximately \$400 million in the initial phases of the centers, using contracts with the center leads.

Overseen by the Biomedical Advanced Research and Development Authority within the HHS Office of the Assistant Secretary for Preparedness and Response, each contract can be renewed for up to 25 years, representing a long-term commitment to this partnership with industry and to national security.

Under the contracts, each consortium will retrofit existing facilities or build new ones to incorporate flexible, innovative manufacturing platforms that can be used to manufacture more than one product. The facilities will use modern cell- and recombinant-based vaccine technologies that have the potential to produce vaccines for not only pandemic influenza but also other threats more quickly and in a more affordable way.

The centers' use of these technologies also will allow each to develop and manufacture a variety of products quickly enough to respond to large-scale emergencies, providing needed domestic surge capacity. Together, the centers will be capable of domestically producing a quarter of the nation's pandemic influenza vaccine within four months of the onset of a pandemic. In 2009, only one company had manufacturing facilities solely in the United States to produce H1N1 pandemic vaccine.

The private partners will provide approximately 35 percent of the total cost of the initial building phase. HHS will support the cost of operation and maintenance of the centers in subsequent years.

As the facilities become operational in 2014 and 2015, the center leads will begin assisting small biotech companies with technology, regulatory affairs, quality systems, and manufacturing expertise to reach the goal of a licensed and readily available product for public and private use. Also at that time, center academic partners will offer advanced training for the next generation of biotechnology workers.

Emergent Manufacturing Operations Baltimore LLC, with facilities in Baltimore and Gaithersburg, Md., will lead one center, working with a network of partners; Michigan State University, Kettering University of Flint, Mich., and the University of Maryland, Baltimore. This contract is for approximately \$163 million over the first eight years.

Novartis will head a second center, leveraging existing public-private investments by HHS in state-of-the-art facilities in Holly Springs, N.C., and working with North Carolina State University and Duke University. The Novartis contract is valued at approximately \$60 million over the first four years.

The Texas A&M University System will lead a third Center collaborating with GlaxoSmithKline Vaccines of Marietta, Pa.; Lonza of Houston, Texas, and Kalon Biotherapeutics of College Station, Texas. This contract is valued at approximately \$176 million over the first five years.

Creating Centers for Innovation in Advanced Development and Manufacturing was recommended in the [2010 Public Health Emergency Medical Countermeasure Enterprise Review](#), a comprehensive, government-wide review called for by Secretary Sebelius when the department encountered challenges developing biodefense medical countermeasures, including the 2009 H1N1 pandemic flu vaccine.

The centers also address concerns raised by the President's Council of Advisors on Science and Technology in the August 2010 [Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza](#) which called for flexible, nimble, and modern vaccine manufacturing technologies.

For more information on national public health and medical preparedness visit www.phe.gov and to learn more about the Centers for Innovation in Advanced Development and Manufacturing as well as other advances in medical countermeasures, visit www.medicalcountermeasures.gov.

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