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DEPARTMENT OF DEFENSE JOINT VACCINE ACQUISITION PROGRAM (DOD-JVAP): CSC'S DYNPORT EDGES ONE STEP CLOSER TO PLAGUE VACCINE

It's lethal. It's extremely contagious. Plague is caused by the Gram-negative bacterium *Yersinia pestis* and is one of the oldest documented infectious diseases. Infections are classified as either bubonic or pneumonic plague depending on the route of transmission (flea bite or aerosol, respectively). Three pandemics of plague have occurred in recorded history, each resulting in enormous morbidity and mortality.

PNEUMONIC PLAGUE: A TERRIFYING BIOLOGICAL WEAPON

As the Working Group on Civilian Biodefense wrote, "The availability of *Y. pestis* around the globe, the capacity for its mass production and aerosol dissemination ... make the use of plague as a biological weapon a great concern." Aerosol exposure leads to sepsis and death much more rapidly than bubonic plague. Within 72 hours of exposure, 100% of pneumonic plague exposures result in death if untreated. Antibiotic therapy is effective only when administered within 18 hours of exposure. If treatment starts at the first sign of disease, it is generally too late for successful intervention.

DYNPORT'S GOAL: A VACCINE TO COMBAT THE TERROR

DynPort Vaccine Company LLC (DVC), on behalf of the Department of Defense Joint Vaccine Acquisition Program (JVAP), is developing a recombinant plague vaccine designed to provide protection against pneumonic plague. Thanks to the dedication and skills of a team of scientists at CSC's DVC, in close partnership with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), and an expert team of subcontractors, the world is one step closer to a pneumonic plague vaccine.

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Answers for Success



In April 2004, DVC announced that it had completed nonclinical testing of its plague vaccine — conceived and developed at USAMRIID, then handed over to DVC for advanced development, testing and licensure. In initial testing, the vaccine protected mice against both bubonic and pneumonic plague.

Explains CSC's Mark Bolanowski, PhD, Principal Investigator leading this effort, "There have been vaccines for plague in the past, but they only protected people against bubonic plague. No vaccine has ever protected against pneumonic plague. DVC's goal is to develop a biodefense vaccine that can protect our defense personnel and civilian population in the event of an attack using *Y. pestis* in aerosol form."

CLINICAL TRIALS BEGAN IN 2005

Following successful nonclinical efficacy and safety studies, DVC began the next step – human clinical trials of the vaccine. DVC initiated Phase 1 clinical trials in 2005 and is poised to complete the first of two Phase 2 clinical trials in 2008, and to initiate the second—and last—Phase 2 study in 2009. The vaccine program has received Fast Track designation and DVC plans to seek FDA approval using the FDA Animal Efficacy Rule.

The plague vaccine is one of a range of biodefense vaccines being developed by DVC under its contract with JVAP. Currently, there is no FDA-licensed plague vaccine.

This product is currently under clinical investigation and has not been licensed by the FDA.



DVC's rF1-V plague vaccine.