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The Pandemic Threat

Given the unpredictable behavior of influenza viruses, neither the timing nor the severity of the next pandemic crisis can be predicted. Although the WHO has issued a six-phased approach for national preparedness and response, the “Pharmaceutical Solution” remains uncertain.

And the dilemma is clear:

- Finding a way to produce millions of doses of vaccines in a matter of weeks to combat varying sub-types of influenza;
- Implementing a plan that effectively executes Phase 3 level preparedness with the pharmaceutical and response capacity to treat millions of citizens in the event that a pandemic wave reaches Phases 4–6.
- And, containing community outbreaks until the crisis’ reaches a post-pandemic phase.

The PhageVax Solution

As noted in the recent Centers for Disease Control and Prevention community planning guidance, the only intervention that can reasonably be expected to control an influenza pandemic is vaccination of a large fraction of the population with a strain-matched vaccine.

The conventional technology of egg-based vaccine production accepts that pandemic influenza vaccine will not be available until many months after the onset of the pandemic. Thus, the fundamental flaw with the current vaccination production and delivery system is that it arrives too late.

PhageVax, a Newark, Ohio-based company has developed a new vaccine production method for combating emerging infectious diseases – including the novel H1N1 swine flu and the deadly H5N1 avian flu. **PhageVax** has created a novel platform to produce vaccines against infectious diseases – from pathogen identification to the scaled manufacture of doses. This process allows for millions of doses to be produced and distributed in a matter of 4 to 6 weeks for both civilian and military personnel.



Traditional vaccine generation, using eggs or other cell-culture or other insect-cell media, typically takes from 4 to 6 months. In that time, it's not uncommon that pathogens mutate, thus rendering the proposed (egg-based or cell-based) vaccines useless.

PhageVax's Bacteriophage-DNA Vaccine Platform represents a "just in time" manufacturing process for combating rapidly evolving infectious diseases. The company's platform technology allows for

production of a vaccine (from the initial identification of a pathogen to a cGMP lot of vaccine capable of protecting tens of millions of people) in literally 1/4 the time of traditional methods and at a fraction of the U.S. Tax-payer's cost compared to egg-based Flu Vaccines.

With **PhageVax's** pharmaceutical solution in place, the next challenge is implementation.

HWI Global's Innovative Mobile Technology

Pittsburgh-based Design-Build Clean Room Contractor, Haddad-Wylie Industries, LLC (**HWI Global**) has developed a concept to meet that challenge. As a turnkey provider for some of the nation's top medical and pharmaceutical institutions, such as the Cleveland Clinic Foundation, AstraZeneca, Duke Hospital, UPMC and others, HWI Global has designed a system that takes the standard *AHRF Design Requirements* for the prototypical mobile BSL-3 laboratory and enhances its performance and flexibility by incorporating a proprietary control and monitoring system unlike anything seen in the industry to date.

An Innovative & "Green" Central Control System

- A custom-programmed PC based control package will minimize a trailer's power consumption by monitoring the activity level in real time and automating its controls through variable frequency drives (VFDs);
- This will allow each trailer to be programmed independently so that their instrumentation will modulate the air circulation to create a "self-balancing" environment;
- Each trailer will be equipped with continuous particle monitoring systems and remote data-logging systems to validate each trailer's level of cleanliness prior to vaccine production or sterile compounding;
- The mobile units will have the capability of operating as a "negative pressure BSL-3" or a "positive pressure IV Prep," all of which can be monitored, programmed and controlled from HWI's central command in Pittsburgh (or from any remote location that the government chooses);

- The result is complete flexibility and full usage of the investment, as these mobile trailers for pandemic crisis' can be utilized for other forms of emergency response, such as disaster relief or simple mobile hospital suites;
- Each unit will be fully equipped as a “central plant,” with stackable (“Green”) air-cooled chillers for redundancy (a zero environmental footprint) and back-up generator capacity;
- **HWI Global** will construct the interior of the units with its patented **Bio-Gard™** wall, ceiling and flooring system, a homogenous, monolithic aseptic product; and it will be fit up with **HWI Global's** custom sterile casework.

A Streamlined Manufacturing Plan

Upon approval of a common design footprint, **HWI Global** will manage an assembly line of production in order to complete the project in one calendar year.

In order to mass-produce the 300 targeted units, HWI Global is partnering with five (5) Pittsburgh-based ISO:9000 manufacturing facilities where assembly and start-up can take place under a strict cGMP validation and quality control process.

We estimate that each of the five (5) facilities can produce 15 units every 3 months, which accomplishes the goal.

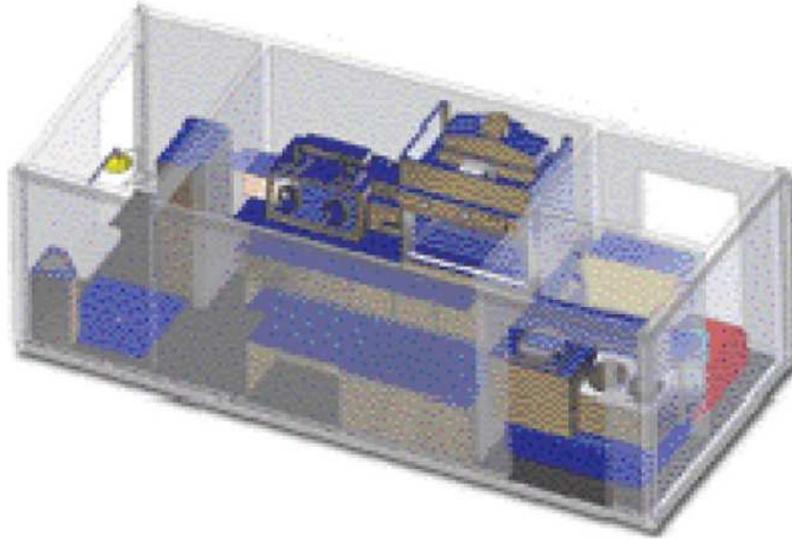
Full-Time Response, Monitoring & Preventive Maintenance

HWI Global will store the units in secure locations and will provide an around-the-clock dispatch program to deliver the units as needed.

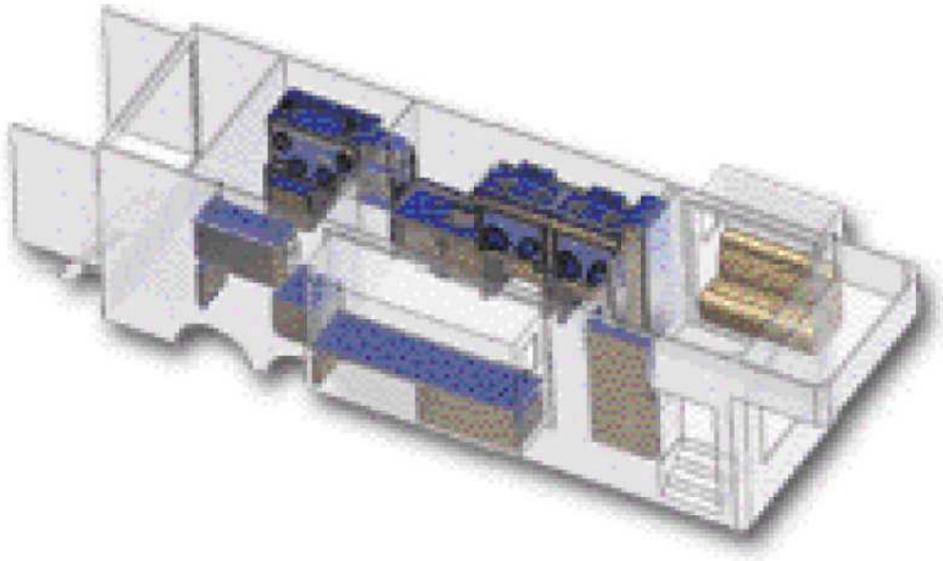
HWI Global will provide a Full-time Maintenance Program and will conduct quarterly certification and calibration of each unit; we will also provide complete DOT maintenance on the trailers.

Estimated Unit Cost

After our thorough evaluation, an estimated turn-key cost for each unit is. . . . **\$2,450,000**



Model 1



Model 2



Model 2 Rendering