RESPIRATORY PROTECTION DEVICES (RPD) & VENTILATORS

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Goals of the RPD & Ventilator Programs

- Ensure critical medical devices needed for response to Influenza Pandemics or CBRN threats are:
  - Available – domestic stockpile or surge capacity
  - Appropriate – the right product
  - Affordable - stockpiling or domestic surge production
Medical Devices Program Line-up

• Stockpile All Hazards Ventilator – Phillips Respironics
• High Speed N95 Manufacturing Line – In Negotiations
AoI#1: Personal Protective Equipment (Mask & Respirators) for Influenza Infection and All-Hazard

- Technical Point of Contact: Rodney Wallace; Rodney.Wallace@hhs.gov

- Priorities:
  - Support improved respiratory protective devices with improved features over currently available products
  - Essential attributes (functionality, usability, comfort, decontamination and re-use, cost efficiency, manufacturing efficiency, and durability)
  - Applicable for all ages (pediatric through adult)

- Data Expectations:
  - Proposed benefit and supporting data
  - Commercialization, regulatory, & manufacturing plans (if applicable)
AoI #2: Full-Featured Continuous Ventilators for Influenza Infection and All-Hazards

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- Priorities:
  - Support advanced development of new or improved ventilator to provide respiratory support in clinical care, transport, and emergency use settings
  - Key considerations include portable support neonate (≥2.5kg) to adult populations, ease of operation, use of universal components, ease of stockpiling/maintenance, provide accessories, low cost (<$3,000), domestic surge production

- Data Expectations
  - TRL 6
  - Prototype / preliminary performance data, commercialization plan, regulatory & manufacturing plans