



United States Department of
Health & Human Services

Office of the Secretary
Office of the Assistant Secretary for
Preparedness and Response (ASPR)

Discussion with Respirator Protection Device Manufacturers on Preparedness and Surge Capacity

November 2007

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Bottom Line

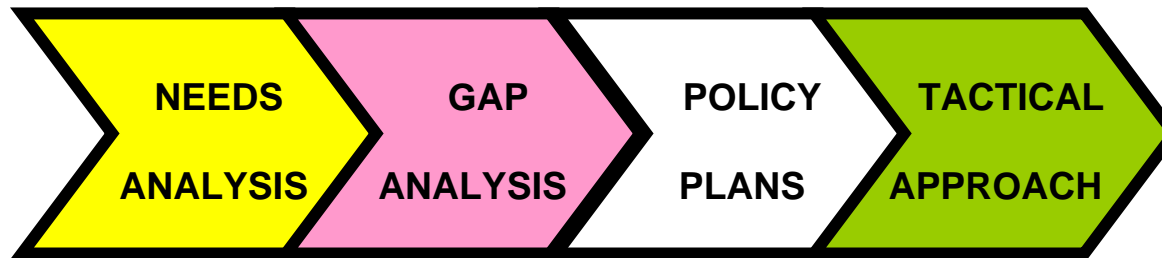
- **There will a significant increase in the need for Respiratory Protection Devices (RPD) during an influenza pandemic**
- **There will be significant needs across all sectors: Health Care (HCW); Public Safety (PSW); Business (BW); Government (GW); and Public (Home Patient Care – HPC and General Public GP)**
- **Industrial surge capacity of RPD will not be able to meet need and supplies will be short during a pandemic**
- **There are several RPD options that can be employed to meet the projected needs**
- **All sectors must contribute to efforts to prepare in order to meet the needs for RPD or find safe ways to work around limited supplies during a pandemic**

BARDA Role in Pandemic Preparedness

- The Biomedical Advanced Research and Development Authority (BARDA) was created by the Pandemic and All-Hazards Preparedness Act (PL 109-417) to develop and make available to the public medical countermeasures for pandemic and emerging diseases
- BARDA reports to the Assistant Secretary for Preparedness Response of HHS
- Current Activities are:
 - Influenza and Emerging Disease Program (IED)
 - Project BioShield (PBS)

IED Program Approach to Countermeasure Analysis and Development

Strategic Acquisition Plan for Pandemic Medical Countermeasures



- Pandemic MCM needs identified (e.g. ventilators)
- Gap analyses of MCM need performed on industrial capacities & government stockpiles
- Policy plans, recommendations & guidance (e.g. shared responsibility) prepared & approved
- Tactical implementation approach developed
 - MCM advanced development
 - MCM stockpile purchases (e.g. federal subsidies)
 - Infrastructure mfg. capacity building (e.g. retrofitting facilities)
 - Warm base operations
 - Misc. (e.g. futures contracts, liability relief, recommendation changes)

Modeling Assumptions on Needs for Respiratory Protection

- Pandemic Severity 5 – worst case scenario
- Normal care standards will not be compromised
- Persons in close contact with patients or suspected patients will use N-95 for respiratory protection
 - Others will be advised to use a surgical mask for protection
 - Patients if possible should wear a surgical mask to cut down on spread
- Cohorting of patients will be done to segregate infected influenza patients from uninfected patients
 - Reduces the need for HCW to change PPE between patients
- A significant percent of the patients will be cared for by individuals in the home
- Emergency medical services, public safety workers, business workers and the general public all have respiratory protection needs

Projected needs models are based on the following inputs

- Current guidance documents on respiratory protection
- Discussions within a cross-Department Working Group on Respiratory Protection
- Current models on patients numbers based on the effectiveness of community mitigation strategies (50% reduction in cases)
- Calculations are based on disposable needs (SM and N95)
 - Reusable options can significantly reduce the numbers

Assumptions for Need of RPD by HCW, PSW, BW and GP (PS-5)

	Rates of Use/Total Need	
	N95 Respirators	Surgical Masks
HCW	1,600M	1,300M
PSW	1,400M	500M
BW	0	8,400M
GP	2,300M	16,700M
TOTAL NEED	5.3B	26.9B

RPD Supplies

- Limited U.S.-based ongoing and surge production makes stockpiling necessary to assure availability for a pandemic
- N95 supply issues
 - Annually ~900M N95 per year available in the U.S.
 - ✓ Most are used in non-medical settings
 - ✓ ~10-20% of annual sales are going to stockpiling
 - ✓ 25-30% produced overseas
 - SNS includes CDRH-cleared and non-cleared (2% of need)
 - Approx.15% of the total N95 supply is CDRH-cleared
 - No N95s available for children
- SM issues
 - Annual production of surgical masks to the U.S. market is ~3.8B
 - ✓ 90% of the domestic supply comes from overseas (Asia)
 - SNS has stockpiled CDRH-cleared SM (0.2% of need)

How can the US
Government develop
and execute a strategy
to address the large
gaps identified?

Conclusions

- **There will a significant increase in the need for Respiratory Protection Devices (RPD) during an influenza pandemic**
- **There will be significant needs across all sectors: Health Care (HCW); Public Safety (PSW); Business (BW); Government (GW); and Public (Home Patient Care – HPC and General Public GP)**
- **Industrial surge capacity of RPD will not be able to meet need and supplies will be short during a pandemic**
- **There are several RPD options (re-usable devices, etc.) that can be employed to meet the projected needs**
- **All sectors must contribute to efforts to prepare in order to meet the needs for RPD during a pandemic**

Questions for Consideration by the RPD Industry

- **Pandemic Preparedness**

- What is your company doing to prepare your staff and facility for a pandemic flu outbreak?
- Have you made preparations for replacement staff or extra staff to increase production lines during the pandemic?
- Do you have plans to address worker absenteeism?
- Are there any plans to cross-train staff in the production lines to compensate for the projected absenteeism at your facility?
- Are there plans to stockpile anti-viral drugs at your facility and to dispense to workers on the production lines?
- Are there any plans for stockpiles of face masks or N-95s for your facility staff?
- What are the barriers to the implementation of a preparedness plan?

Questions for Consideration by the RPD Industry

- **Production Preparedness**
 - What is your current surge capacity?
 - How sustainable is your surge capacity?
 - Is your supply chain for domestic production sustainable during a pandemic?
 - Are you dependent on imported materials?
 - What raw materials are essential to your production lines?
 - Can the essential raw materials be stockpiled or produced domestically?
 - Do you have plans to increase your domestic production/surge capacity?
 - What are the conditions necessary for increasing your domestic production/surge capacity?
 - What are the barriers to increasing your domestic production/surge capacity?
 - What would make this growth sustainable?

Questions for Consideration by the RPD Industry

- **Product Preparedness**

- What are the barriers to getting devices FDA-cleared?
- What incentives would you suggest to encourage FDA-clearance of devices?
- Can product shelf life be extended?
- Are there barriers that prevent shelf life extension?
- What incentives would you suggest to encourage shelf life extension?
- Are there new products in development suitable for pandemic use or stockpiling?
- What would encourage the development of devices suitable for pandemic use or stockpiling?
- If you produce re-usable devices, how could they play a role?

Questions for Consideration by the RPD Industry

- **Public Preparedness**

- What measures has your company taken to train the general public or healthcare professionals for fit-testing of your products?
- What ideas do you suggest for education of the public on the use of surgical masks and N-95 respirators during a pandemic?
- Are there other devices that you offer that could help meet the need for respiratory protection?
- Could you suggest any ideas for the use of these alternative devices?
- Are there ideas that you would suggest to encourage stockpiling by the general public?

Contact Information

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Thank You for your time!