An Emergency Services Coalition for Medical Preparedness Discussion Document

March 2013

Stockpiling - Back to the Basics

Background

- The current pharmaceutical and medical supply system fails to provide consumers optimal health outcomes of availability, price and certainty;
- Long term investment in pharmaceutical and medical device research and development in the US is rapidly disappearing overseas;
- Both Active Pharmaceutical Ingredient (API) and molecule manufacture are predominantly housed in China, leaving the U.S. market subject to interruption;
- The Strategic National Stockpile is operating a model that is 10 years behind current supply chain best practices;
- BioShield reauthorization and FDA reform present opportunities to increase resilience at the community level.

Discussion

With the recent passage of the Pandemic and All-Hazard Preparedness Act of 2013, the US Congress signaled bipartisan support for enhancing the US response to and recovery from all-hazard threats. Congress has also indicated it is interested in leaner, more efficient medical and health security programs. Fifteen years after the Nunn-Lugar national security era programs were established it is a time to return to the basics of medical preparedness, while remaining vigilant against new threats. Three areas are worthy of immediate policy consideration:

1. Refocus the Strategic National Stockpile operations;
2. Realign the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to ensure private sector financing, manufacturing and supply chain practices and efficiencies are drivers in the development, acquisition and distribution of countermeasures; and
3. Establish a new Strategic Medical Supply System (SMSS) to mitigate the current national security gap.

Refocus the SNS operation as a support system for community- caching of critical medical supplies. Much has changed since the SNS' founding in 1998.The SNS model has not been sufficiently reviewed and revised to reflect the expectations of a society in which the majority of flu vaccines are delivered in "minute clinics" and grocery stores, and mail delivery of pharmaceuticals ordered online is normal. Massive federal warehousing needs to be refashioned into a support system for community-based medical supplies that can be leveraged by community emergency asset managers in league with private sector partners. Resilience at the community level is core to our national security, re-focusing the SNS at this time would re-establish its basic mission.

The Chempack program, which placed medical countermeasures in strategic locations across the country – giving first responders quick access to them in the

event of a chemical attack on an American city – has been a success. The program is in jeopardy as caches are not replaced. Innovative thinking such as this must continue so that medical countermeasures are available to local incident command staff, first responders, and their families.

Realign the PHEMCE to ensure private sector innovation can flourish. The Federal government alone cannot hope to achieve the goals it has set for itself in the Pandemic and All-Hazard Preparedness Act of 2013 unless it significantly enhances cooperation and coordination with and between the private sector capabilities in the US.

The nation has responded well to numerous East Coast hurricanes in recent years, but Katrina, Sandy and the Haiti earthquake, demonstrate there are significant gaps. Chronically ill persons have been medically compromised during disasters because their medical supplies are lost during evacuation. Responders and victims alike who require tetanus vaccinations must wait for days for supplies to arrive from other parts of the US. Critical natural resources required in the manufacture of pharmaceuticals are in short supply due to international demand (especially critical in a pandemic scenario), etc. The only way to overcome these issues and increase the Nation's response and recovery capability is to immediately enhance the Federal government's communication with the private sector. Legal constraints (anti-trust, liability, etc.) must be addressed, but those alone cannot be an excuse for maintaining the status quo.

Updating current medical supply practices in face of current conditions will not be sufficient, we also recommend the establishment of a Strategic Medical Supply System (SMSS). This is a national security imperative to address the overlapping, ambiguous responsibility of federal agencies, combined with longstanding changes in the capital formation of the U.S. pharmaceutical industry, which leave us vulnerable. The SMSS will contribute to overall healthcare cost containment, by ensuring drugs are available at the right place to the right people at the right time, the SMSS will be a dual-use capacity, functioning in times of peace and strife. The SMSS could jumpstart the exploration of a new generation of antibiotics, the lack of a new product in the last 15 years leaves us vulnerable on many fronts.

Conclusion

The authorization of the Pandemic and All-Hazards Preparedness Act of 2013 is a reason for optimism, and a great opportunity for the HHS Assistant Secretary for Preparedness and Response to provide " integrated policy coordination and strategic direction with respect to all matters related to federal public health and medical preparedness." To ensure that this authorization is backed with sufficient appropriations to protect the nation it will be necessary to demonstrate new ways of conducting business. The "protection of the protectors" being a primary example.

Suggested Next Steps

1. Quickly engage logistics expertise to reengineer the Strategic National Stockpile as well as other response entities in the Federal government (MMRS, DMAT, etc.);

2. Engage the Emergency Services Sector in discussions concerning next steps in preparedness such as voluntary vaccination programs for anthrax and smallpox; enhanced and innovative storage solutions for medical countermeasures held locally, and align the SNS with local incident management conditions.
3. Hold quarterly government sponsored meetings with operational experts (local emergency services, drug manufacturers, suppliers, transportation companies), and explore alternate financing mechanisms to shorten the supply pipeline from concept to licensure for medical countermeasures;
4. Develop a dedicated user requirements and standards development capacity from the ranks of emergency services, the InterAgency Board, healthcare distributors, hospitals and public health authorities;
5. Reduce the Strategic National Stockpile Push Packages from current numbers to eight by 2015 and work with State and local emergency services to forward deploy and redistribute the medical countermeasures to better protect local capacity.