INNOVATION SUPPORTS FEDERAL COVID-19 RESPONSE

A Case Study on Short-term Results and Sustainment Thoughts

By John Bartrum, NAPA Fellow

Dr. Deming noted "…it is necessary to innovate, to predict needs of the customer."[i] During the COVID-19 Pandemic, we have seen yet again how necessity is the mother of innovation.

History doesn't repeat itself, but it rhymes. Technology advances have been used to address many human challenges experienced throughout history. Infectious diseases can be propagated by bacteria, viruses and other things you cannot see. For example, smallpox used to kill millions. In 1796, Edward Jenner decided to try an experiment that resulted in a new technology: a vaccine for smallpox[ii]. Sir Alexander Fleming harnessed the power of nature to establish the single greatest victory over disease in the 1920s with the discovery of penicillin[iii]. Technological advances have impacted how we treat illnesses, but does not change the fact that infectious diseases have the potential to make people sick, or as in 1918 and 2020, threaten the entire human race. It is only through innovation that we can both reduce and overcome these real threats.

What is innovation? Innovation is the action or process of innovating a new method, idea, or product. Often, it is making new things with things you already have. Innovation occurs at two different levels – breakthrough and incremental – both are needed but breakthrough requires more deliberate leadership focus.

- **Breakthrough:** Innovation that shakes up an industry by suddenly reimagining how to approach or solve a problem.
- **Incremental:** Innovation occurring everywhere, often in small but significant changes, through leveraging new technologies and business models to drive down costs, increase accessibility, and improve services.

Public perception has assumed that government organizations are incapable of a culture of innovation as they are absent of competitive forces, lack of incentives for employees, and have excessive red tape. However, innovation does and has occurred in the government. Historically and as the COVID-19 pandemic response highlights, we see when leaders make a deliberate decision to focus on innovation, they can overcome this conventional wisdom.

In WW II, after the creation of Eighth Air Force, US Brigadier General Ira Eaker implemented the first sustained day light bombing strategy over Europe from England. The strategy and procedures were refined with innovative approaches that went beyond incremental changes to achieve success. For example, General LeMay (then Colonel LeMay) implemented a staggered

formation tactic to consolidate defensive fire power for the B-17 aircraft. This breakthrough innovative change was critical to the long-term success of the mission.

Similarly, Dr. Robert Kadlec, the Assistant Secretary for Preparedness and Response (ASPR) reorganized ASPR upon his arrival in 2017 and made decisions with a focus on supporting, encouraging, and locating innovative breakthrough technology to save American lives. These efforts are already bearing fruit to support the COVID-19 pandemic response.

Dr. Kadlec created the ASPR Strategic Innovation and Emerging Technology function under the leadership of Joe Hamel. Dr. Kadlec reinvigorated the ASPR Biomedical Advanced Research and Development Authority (BARDA) innovation process with the launch of DRIVe. These pivotal actions not only signaled the need for a new strategy to his team but to the private sector enterprise on how important it was to go forward with innovative technologies.

The ASPR Strategic Innovation and Emerging Technology office began the process to create mechanisms to experiment, address an outdated procedural infrastructure with flexible mechanisms, and reach out to new disciplines and partners. This promoted product and service improvement opportunities to address future challenges that had heretofore been unaddressed. For example, even before the COVID-19 vaccines were being developed, it was known that there was a potential shortage of glass vials and needles for those vaccines. An innovative partnership with a public benefit organization, allowed for an opportunity to repurpose an existing technology. The Rapid Aseptic Packaging of Injectable Drugs (RAPID) is a consortium, which has accelerated the building of a new U.S.-based, high-speed, population-scale emergency drug injection capability with prefilled syringes to leap over the challenge by repurposing an existing technology to create a new type of pre-filled syringes. An additional benefit was the ability to reduce the risk of shortages due to a dependance on foreign manufactures.

ASPR empowered its partners with existing flexible funding mechanisms to rapidly develop and support the start of a cultural change. In addition, Dr. Kadlec began the process to build innovation focused processes and procedures into the ASPR strategic mindset itself. It is too early to know if the long-term adoption of these groundbreaking innovation cultural shifts will become fully incorporated in to this organization. Long-term cultural change is a long road but it is clear the foundation has begun. These efforts during the COVID-19 pandemic has shown how the strategic leadership focus on innovation is already providing valuable returns to the public.

> The ASPR is responsible for the advanced research and development, and coordinated acceleration and fielding of, medical countermeasures and life-saving products.

The fruits of these efforts have not been routinely advertised on the front page of the newspaper, especially how the seeds were laid. Several of the flexible mechanisms developed by the leadership to promote innovation include:

- **DRIVe:** A program to accelerate the development and availability of transformative technologies and approaches to protect Americans from health security threats. The program is located within ASPR Biomedical Advanced Research and Development Authority (BARDA) to fertilize seedling innovation efforts aimed at building new technologies and approaches using innovation with medical countermeasures.
- **ASPR Program Executive Office for Industry and Innovation (PEO-AI2)**: Supports all ASPR activities to work with and coordinate across industry, private sector, and government organizations to identify, promote, facilitate, and implement innovative breakthrough solutions to support the ASPR mission.
- **Strategic National Stockpile (SNS)**: The move of the SNS to ASPR allowed for a review of its program and authorities to enhance innovative approaches. The effort resulted in the development of novel platforms for distributed pharmaceutical production, administration of vaccines and deployment of ground-breaking medical equipment to support ASPR's mission to save lives.

Innovation does and has occurred in the public sector if given active and extreme leadership support. Dr. Deming, famous for modern innovation theory and practice, noted how organizations should create consistency of purpose toward improvement and to improve themselves constantly and forever. Thus, in the long-term, an organization like ASPR will need to enhance its culture to not only promote rapid breakthrough innovation but also make incremental innovative steps within its internal and external public partnerships.

Dr. Kadlec's initial reinvigoration of ASPR appears to have focused initially on breakthrough technologies to provide the initial energy with rapid and effective wins to advance a broader culture of innovation. ASPR's initial efforts, in my opinion, dramatically enhanced its ability to support the government-wide health response to the COVID-19 pandemic. These new programs, projects, and relationships have served as a springboard to support the COVID-19 pandemic response.

Specifically, Dr. Kadlec's ASPR's Strategic Innovation and Emerging Technology office, now PEO-AI2, has been crucial in the fight against the COVID-19 pandemic. The following are some of the programs and impacts:

ASPR Renal Dialysis Care[iv]	ASPR deployed new renal dialysis technology to care for patients with COVID-19. • Launching the program through a partnership with the PEO-AI2 office and the SNS, ASPR deployed these platform machines that use tap water to produce the solution necessary for dialysis on demand to homes of Americans. • Impact: Reduced demand for dialysis supplies and provided supportive care to dialysis patients during the height of the pandemic.
RAPID Consortium[v]	ASPR created a new consortium for Rapid Aseptic Packaging of Injectable Drugs (RAPID) to create a capability that will enable the SNS to fill and finish, on a rapid basis, hundreds of millions of pre-filled syringes to respond quickly and efficiently to widespread health emergencies.

	• The partnership with Apiject, Inc. is accelerating the building of a new U.S.-based, high-speed, population-scale emergency drug injection capability with prefilled syringes. • Impact: The effort leverages a well-established technology, called Blow-Fill-Seal, into a new field to allow the SNS to reduce its reliance on limited glass vial manufacturing capacity, increase fill capacity, and reduce reliance on foreign dependance for supplies with limited surge capacity.
Public Private Partnerships Speed Response Efforts[vi]	ASPR established public private partnerships through donation agreements. • Impact: Enabled ventilator, diagnostic and dialysis machine makers to produce critical equipment at incredible scales, through the establishment of www.meddevicenetwork.org, in collaboration with AdvaMed and the Aerospace Industry Association.
Priority Medicines on Demand[vii]	ASPR is developing a highly distributed on-demand manufacturing capability for supportive care fluids. • Initial focus is on hospital grade Saline used for injection; it is expected to expand to other medical products. • Impact: The ASPR collaboration with the Defense Advanced Research Projects Agency (DARPA), has resulted in an effort to produce critical ICU medicines in shortage with a novel synthetic chemistry platform.
HHS Foundry for American Biotechnology[viii]	ASPR in partnership with the Advanced Regenerative Manufacturing Institute, established the Foundry for American Biotechnology (ARMI NextFAB). • Impact: Established a public-private partnership to produce technological solutions to help the U.S. protect against and to respond to health security threats, enhance daily medical care, and add to the U.S. bioeconomy. o Expects to attract additional private sector funding and to commercialize the foundry's innovation projects. o Partners include industrial pharmaceutical and industrial automation sectors.

In addition, the COVID-19 pandemic response has benefited from the relationships and understanding of how the private sector operates. This was seen in part as Joe Hamel led the ASPR portion of the government wide Industrial Base Expansion efforts with his Department of Defense partners.

What additional approaches and questions can ASPR, or other government agencies, use to ensure its initial success is leveraged into a broader cultural innovative mindset?

<u>*First,*</u> promote and grow the leadership team with an extreme focus on innovation at the breakthrough level first while deliberately building incremental innovation. For example, ASPR should leverage the guidance of PEO-AI2, SNS and DRIVe across all its programs and offices.

<u>*Second,*</u> foster programs with the design elements:

- Creativity: Serve as a spark for innovation that solves tangible problems
- Design Thinking: Research to understand the challenges to develop solutions – look outside the conventional silos.

- Fail Fast: Promote quick prototypes, accept failure and utilize the lessons to revise the prototype. If it is not working – pull out and then move forward but learn from the effort.
- Problem Solving: Identify solutions that solve problems.
- Implementation is Key: Solutions must be scalable, monitored, and the return on investment must be tracked.

Third, use Innovation Project Business Case efforts to track continued long-term success. Identify the standards for problems being solved with breakthrough goals, benefits, cost, potential obstacles, milestones, and metrics but also seek out:

- New paths and mechanisms to provide a competitive edge.
- Expertise and innovative partners with cross disciplinary teams or those with a different perspective.
- Enhance efforts to motivate, communicate, and collaborate across the ASPR programs, innovative partners, and with other federal agencies.
- Haste and speed are not the same. Focus on speed with projects that are well thought out, properly planned, and designed for rapid execution.
- Root Cause: Ensure projects attack the root of the problems – not just a symptom.

How to promote cultural adoption?

On the cultural adoption and expansion approach in ASPR or other public organizations, a few concepts to consider during the journey:

- Develop extreme leadership support. Go beyond mere words or words on paper with approval of a program office and procedures.
    - Leadership must demonstrate how they are integrated in the innovation efforts
    - Actively leverage the organization's planning, programming, and requirements processes.
- Promote breakthrough and incremental innovation from the day-to-day work of the organization.
- Celebrate wins, especially small wins.
- Implement ways to foster ideals – in informal settings and attracting outside speakers to promote and energize creative and enhanced thinking.
- Promote internal experiments to test and try ideals – celebrate lessons learned from failure as progress to success.
- Promote possibility thinking and scenario planning – if you believe you can accomplish something the probability of success increases.

Change will not happen overnight, ASPR should be applauded for its early success. Its efforts have made considerable progress toward pushing the envelope to an innovation focused culture but is not yet done. In fact, innovation is a continuous journey not a destination. The efforts of Dr. Kadlec and the ASPR team have achieved incredible short-term successes to support the battle against the COVID-19 pandemic. The focused effort must be sustained to enhance its ability to win the war against this pandemic and future threats to our nation.

About the Author: John Bartrum, J.D., MBA, is a National Academy of Public Administration Fellow. The CEO of Brightstar Innovations Group, LLC, a Capitol Hill veteran and retired federal Senior Executive Service career

official with over 36 years of federal appropriations, healthcare, life science, defense, and veterans affairs experience. An Air Force Brigadier General, John is the Reserve Mobilization Assistant to the Air Force Deputy Surgeon General. In 2020, he was mobilized for seven months as the Government-wide COVID-19 Deputy Incident Manager with HHS and FEMA. The views expressed in the article are the author's and do not represent those of the Government.

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