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DATE AND TIME

Monday, April 22, 2024

8 a.m. ET to 4:30 p.m. ET

LOCATION

Constitution Center
400 7th St, SW, Washington DC



n behalf of ASPR's Center for Industrial Base Management and Supply Chain (IBMSC), welcome to IBMSC's inaugural Industry Summit!

We are thrilled that you are here, and we hope this is the start of many more successful IBMSC- Industry collaborations. Today's Summit brings together visionaries, leaders, and "movers and shakers" across Government, Industry, Innovation, Technology, Academia, and more. Thank you for being a part of this exciting day! The IBMSC Industry Summit offers a unique opportunity for our organization to share, learn, and collaborate with our partners – YOU. These connections are critical in establishing and sustaining a strong and resilient public healthcare supply chain. Our shared preparedness and resilience efforts are more important than ever amidst global unrest, supply chain instability, and inevitable natural and human made disasters. Our shared responsibility to secure our nation's preparedness against these disruptions is what drives IBMSC's mission: building a diverse, agile, public health supply chain through Industry partnerships.

Together, we can operationalize novel solutions for our nation's response, recovery, and preparedness posture.

Thank you again for being an integral part of the collaboration and thank you for joining us at IBMSC's Industry Summit! It's truly wonderful to meet you in person! I encourage you to ask questions, share your vision, evaluate our shared challenges and opportunities, and continue to build on our strong partnerships.



Sincerely,

Arlene Joyner

Deputy Assistant Secretary

Director, Office of Industrial Base Management
and Supply Chain HHS Administration for Strategic

Agenda

8:50 AM Welcome Address: Wayland Coker, Director, Supply Chain Optimization 9:00 AM Industry Partner Reflection: Dean Kamen, Founder, DEKA Research & Development Corporation 9:20 AM **Keynote Address and Fireside Chat:** Dawn O'Connell, Assistant Secretary for Preparedness and Response (ASPR) Arlene Joyner, Deputy Assistant Secretary (DAS), Director of IBMSC 10:00 AM Building and Preserving a Resilient Medical Industrial Base: Arlene Joyner, DAS, Director of IBMSC DPA-ERA: Accelerate, Expand, and Preserve the Public Health Supply Chain (Collaborative Discussion): 10:20 AM Paige Ezernack, Director, Defense ProductionAct and Emergency Response Authorities (DPA-ERA) **BREAK** 10:50 AM 11:00 AM ASPR Contracting: PromotingPublic-Private Partnership through Acquisition Excellence (Collaborative Discussion): Makoto Braxton, Head of Contracting Activity, ASPR 11:30 AM The BioMap-Consortium: Strategic Partnerships (Collaborative Discussion): Brooke Luck, BARDA 12:00 PM LUNCH 1:00 PM Address from Nikki Bratcher-Bowman, Principal Deputy Assistant Secretary and Chief Operating Officer, **HHS ASPR** 1:15 PM **External Partners Panel** Joe Hamel, IBMSC Acting Deputy Director and Director, Enabling Innovations and Technology (EIT)

- Sean Christiansen, Deputy Chief of Staff for the National Economic Council, White House
- Tammy Beckham, Director, Office of Supply Chain Resilience, U.S. Food and Drug Administration (FDA)
- Jason Bolton, Senior Trade and Industry Analyst, Bureau of Industry and Security, Dept. of Commerce
- Sharon Arnold, Supply Chain Resilience and Shortages Coordinator, HHS/ASPE
- Linda Rouse O'Neill, Senior VP, Supply Chain Policy, Health Industry Distributors Association (HIDA)

2:00 PM

Breakout Session 1

- Supply Chain Optimization: Enabling a Resilient Industrial Base. (Wayland Coker)
- Enabling Innovations and Technology (formerly Advanced Manufacturing Technologies): Pharmaceutical Supply Chain Risks and Agile Manufacturing-Future of On-Shoring, a Government Perspective. (Joe Hamel)
- Critical Medical Equipment: Strategic Vision for PPE and Medical Equipment Preparedness. (Jesse
- Testing and Diagnostics: Pivoting Toward Preparedness in a Threat Agnostic Landscape: Optimizing Capacity, Scalability and Flexibility for Unknown Demand. (Matt Humbard, PhD)

2:50 PM 3:00 PM

BREAK

Breakout Session 2

- Supply Chain Optimization: Supporting Domestic Manufacturing: A Government-Industry Working Session. (Wayland Coker)
- Enabling Innovations and Technology: Supply Chain Risks and Agile Manufacturing-Future of On-**Shoring, an Industry Perspective**. (Joe Hamel)
- Critical Medical Equipment: Strategic Vision for PPE and Medical Equipment Preparedness. (Jesse Hawkins)
- Testing and Diagnostics: Overcoming Challenges and Barriers to Facilitate Collaboration: Sharing Essential Resources, Expertise and Data to Combat Future Pandemics. (Matt Humbard, PhD)

3:50 PM

BREAK

4:00 PM

Summary and Closing Remarks: Arlene Joyner, DAS, Director of IBMSC

Guest Speaker Biographies

Dawn O'Connell, Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services (HHS)



Ms. Dawn O'Connell serves as the Assistant Secretary for Preparedness and Response within HHS. She leads the Adminstration for Strategic Preparedness and Response and serves as the Secretary's principal advisor on public health emergencies. Her organization leads the nation in preventing, responding to, and recovering from the adverse health effects of man-made and naturally occurring disasters.

The organization coordinates interagency activities between HHS, other federal agencies, and state and local officials responsible for emergency preparedness and the protection of the civilian population from public health emergencies.

Prior to this role, Ms. O'Connell served as the Senior Counselor to Secretary Becerra for COVID-19. She was also the Director of the US Office for the Coalition for Epidemic Preparedness and Innovation (CEPI), a global partnership to develop vaccines to stop future epidemics. As Director, she was responsible for managing the broad spectrum of CEPI's U.S. and North American interests including its relationships with U.S. and North American-based stakeholders, government entities, and industry partners.

O'Connell served as a Senior Counselor to Secretary Sylvia Burwell and Deputy Chief of Staff to Secretary Sebelius at HHS during the Obama-Biden Administration. In these roles, O'Connell advised the Secretaries on high-priority domestic policy, global health and humanitarian issues, including infectious diseases, public health emergencies, and refugees. She worked with HHS leaders, the White House, and other federal and international partners, to resolve key policy challenges, lead implementation, and drive progress toward Administration goals. O'Connell received a Bachelor of Arts in Literature from Vanderbilt University and a Juris Doctor from Tulane University School of Law. She is an avid runner, and lives in Washington, DC with her husband Ben and two daughters, Frannie and Maddie.

Nikki Bratcher-Bowman, Principal Deputy Assistant Secretary and Chief Operating Officer, HHS Administration for Strategic Preparedness and Response (ASPR)



Mrs. Nikki Bratcher-Bowman is the Principal Deputy Assistant Secretary for Preparedness and Response and Chief Operating Officer for HHS ASPR.

Mrs. Bratcher-Bowman served as the Acting Assistant Secretary for the Administration for Strategic Preparedness and Response from January through June 2021. During that time, she led ASPR as it continued to respond to the COVID-19 pandemic by expanding the use of monoclonal antibody therapeutics; deploying responders from the National Disaster Medical System (NDMS) to serve in hard-hit areas of the country; and continuing to develop, procure, and deploy the medical countermeasures needed to respond to the pandemic.

Mrs. Bratcher-Bowman led the transformation and modernization of ASPR operations and services. She led communications strategy, budget, acquisitions, and congressional oversight. She has served as the Executive Officer of the Office of Intergovernmental and External Affairs (IEA) within HHS. She was responsible for managing and leading IEA's budget and financial resources, human resources, information technology, facilities management, travel programs, contracts and acquisitions, records management, emergency preparedness and safety, freedom of information act oversight, ethics, and information resources across a geographically dispersed organizations. With broad experience in the federal sector, her work has spanned operations, human capital, performance optimization, organizational efficiency and effectiveness, and policy.

Mrs. Bratcher-Bowman has worked within HHS for more than 32 years and has held other positions, including Chief Operating Officer, Senior Advisor, Senior Dispute Resolution Specialist, Labor Relations, Employee Relations Officer, Policy Advisor and Budget Analyst. She is a seasoned collaborative relationship-builder, effective manager, and multi- audience communicator, with experience working in complex organizations and with federal, state, local and tribal officials and public policy groups.

Mrs. Bratcher-Bowman has received numerous awards and recognition for her leadership and service, including the HHS Secretary's Award for Excellence in Management - one of the highest honors given at HHS. Mrs. Bratcher-Bowman is a graduate of the Federal Executive Institute and Liberty University.

Dean Kamen, Founder, DEKA Research & Development Corporation



Dean Kamen is an inventor, an entrepreneur, and a tireless advocate for science and technology. His roles as inventor and advocate are intertwined—his own passion for technology and its practical uses has driven his personal determination to spread the word about technology's virtues and by so doing to change the culture of the United States.

As an inventor, he holds more than 1000 U.S. and foreign patents, many of them for innovative medical devices that have expanded the frontiers of health care worldwide. While still a college undergraduate, he invented the first wearable infusion pump, which rapidly gained acceptance from such diverse medical specialties as oncology, neonatology, and endocrinology. In 1976, he founded his first medical device company, AutoSyringe, Inc., to manufacture and market the pumps. Then,

working with leading diabetes researchers, Dean pioneered the design and adoption of the first portable insulin pump. It was quickly dem onstrated that using a pump could much more effectively control patients' blood glucose levels. At age 30, he sold AutoSyringe to Baxter Healthcare Corporation.

Following the sale of AutoSyringe, Inc., he founded DEKA Research & Development Corporation to develop internally generated inventions as well as to provide research and development for major corporate clients. Kamen led DEKA's development of the HomeChoiceTM peritoneal dialysis system for Baxter International Inc. The

HomeChoic eTM system allows patients to be dialyzed in the privacy and comfort of their home and quickly became the worldwide market leader. Kamen also led the development of technology to improve slide preparation for the CYTYC (now Hologic Inc.) ThinPrep® Pap Test. Kamen-led DEKA teams have also developed critical components of the UVARTM XTSTM System, an extracorporeal photophereisis device marketed by Therakos, a unit of Johnson & Johnson, for treatment of T-Cell lymphoma. An advanced prosthetic arm in development for DARPA should advance the quality of life for returning injured soldiers. Other notable developments include the HydroflexTM surgical irrigation pump for

C.R. Bard, the CrownTM stent, an improvement to the original Palmaz-Schatz stent, for Johnson & Johnson, the iBOTTM mobility device, and the Segway® Human Transporter.

Kamen has received many awards for his efforts. Notably, Kamen was awarded the National Medal of Technology in 2000. Presented by President Clinton, this award was in recognition for invention that have advanced medical care worldwide, and for innovative and imaginative leadership in awakening America to the excitement of science and technology. Kamen was elected a member of the National Academy of Engineering in 1997. He was awarded the Lemelson-MIT Prize in 2002 and was inducted into the National Inventors Hall of Fame in May 2005. He is a Fellow of the American Institute for Medical & Biological Engineering, as well as many other national and international engineering organizations.

In addition to DEKA, one of Dean's proudest accomplishments is founding FIRST (For Inspiration and Recognition of Science and Technology), an organization dedicated to motivating the next generation to become science and technology leaders and build a better world. Founded in 1989, FIRST robotics programs have served more than 3.2 million young people, ages 4 to 18, in more than 100 countries around the globe. Alumni of life-changing FIRST programs gain access to exclusive scholarships, internships and other opportunities that create connections and open pathways to a wide variety of careers.

IBMSC Leadership & Offices

Arlene Joyner

Deputy Assistant Secretary

Director, Office of Industrial Base Management and Supply Chain HHS

Administration for Strategic Preparedness and Response



Ms. Arlene Joyner is the Director of the Industrial Base Management and Supply Chain for the HHS ASPR. In this role, she is responsible for leading HHS efforts on Advanced Manufacturing Technologies, Personal Protective Equipment, Testing and Diagnostics, and Supply Chain Optimization.

Ms. Joyner's previous roles within ASPR include Deputy Director for the Pharmaceutical Countermeasures Infrastructure Division and Branch Chief for the Pharmaceutical Countermeasure Infrastructure (PCI) Department within the Biomedical Advanced Research and Development Authority (BARDA) where she started her federal service 11 years ago in 2011. Prior

to joining ASPR, Ms. Joyner worked for six years at Merck and Company in Quality Auditing and Vaccine Manufacturing Operations, and 16 years at Baxter Vaccines Division as a Manufacturing Manager, Materials Management and Supply Chain Manager, and Manufacturing Operations Director. Ms. Joyner holds a Bachelor's degree in Chemical Engineering from Penn State University and a Master of Science in Chemical Engineering from Villanova University.

Jesse Hawkins, Director, Critical Medical Equipment (CME)

The COVID-19 pandemic has highlighted critical vulnerabilities in the global public health supply chain, particularly in the provisioning of CME, testing materials, and vaccine production capabilities. These challenges underscore the importance of enhancing supply chain resilience to prevent future public health crises from escalating due to similar logistical failures. During public health emergencies, CME plays a role in safeguarding patients, healthcare workers, and the community, despite any logistical challenges.

The COVID-19 pandemic serves as a stark reminder of the need for comprehensive strategies to enhance supply chain resilience against future public health emergencies. By addressing the identified vulnerabilities and implementing strategic initiatives, it is possible to build a more robust, agile, and transparent supply chain capable of responding effectively to global health crises.

Paige Ezernack, Director, Defense Production Act and Emergency Response Authorities (DPA-ERA)



The DPA-ERA office leads, manages, and centralizes ASPR-related legal and legislative requirement activities. This Branch also functions as the HHS DPA Title I, III and VII office.

The DPA-ERA Branch manages the authorities listed above on behalf of HHS and the Secretary. Leveraging these essential DPA authorities and the legislative mandates helps better prepare for, and respond to, public health emergencies like COVID-19, RSV, and the recent infant formula shortage. These subject matter experts also engage with stakeholders across the health resource supply chain to identify constraints and challenges.

Joe Hamel, Acting Deputy Director, IBMSC and Director, Enabling Innovations (EIT) and Technology (EIT)



The EIT office is a component of IBMSC that significantly contributes to strengthening the Domestic U.S. manufacturing capabilities and ensuring resilient supply chain for public health emergencies. EIT leads the efforts to enable, engage and enhance domestic supplies of and improved access to critical drug substances and drug products.

The EIT Office advances the development and deployment of platform technology that 1) enables on-demand, continuous cGMP compliant production of pharmaceuticals, and 2) enables distributed on-demand production of cGMP compliant supportive care fluids. Continuing innovation,

development, and commercial deployment of these platforms will enable distributed domestic drug substance and drug product manufacturing. At the same time, these platforms will help strengthen supply chain resilience, grow the bioeconomy, and deploy increasingly renewable and sustainable pharmaceutical resources capable of immediately responding to surges in demand caused by public health emergencies.

Wayland Coker, Director, Supply Chain Optimization (SCO)



The role of the SCO office is to create a program of activity that seeks the most vulnerable healthcare and public health supply chains within U.S. and identify courses of action to mitigate risks of disruption, lessen supply chain vulnerabilities, and increase our national medical supply chain resilience.

SCO's efforts help ensure national HPH sector capacities are preserved, economically viable, resistant to disruption, and kept competitive in the global marketplace so that these producers/distributors are ready to respond to the next emergency when called upon.

Matt Humbard, Director, Testing and Diagnostic (TDx)



The Covid-19 pandemic made it abundantly clear how important a robust and resilient public health industrial base is to ensure the health and security of the country. ASPR focuses on expanding, securing, and building resiliency across the entire public health and medical industrial base. It is our mission to ensure the continuity and supply chain resiliency of medical diagnostic supplies for biological threats that endanger the nation's health security. Testing and diagnostics are vital part of this mission.

Through extensive engagement with industry, we are committed to building and maintaining a reliable testing ecosystem by creating public and private sector partnerships through the

exchange of information on threats, system vulnerabilities, and potential resources. Our engagement with industry seeks to build relationships that drive innovative and create transformative changes to public health planning and coordination. We look forward to continuing this mission with continued support and cooperation from our federal and private sector industry partners.

Summit meeting documents and video recordings will be posted online:



Thank you for attending IBMSC's inaugural Industry Summit! We hope to see you next year.

Let's keep the conversations going! Request a meeting with IBMSC through IBx Connect today to share your product's potential to address health security challenges.

Industrial Base Expansion (IBx) Connect

Industrial Base Expansion (IBx) Connect is used to coordinate specific strategic innovation and industrial base expansion efforts across ASPR, federal partners, academia, and the private sector. Our goal is to work with the private sector on novel solutions and practices for response and recovery operations and bring them to life.



IBx Connect meetings are for Market Research purposes only and are not considered submissions for potential funding.