

**[00:00:04.25**

Good morning. I'm Chris Hopkins, the director of BARDA's Division of Chemical, Biological, Radiological and Nuclear Medical Countermeasures, and I am delighted to have the opportunity to tell you about some of the great things that our team of scientists, physicians, engineers and analysts have accomplished over the past year.

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And more importantly, to give you some insight regarding even bigger things that we hope to accomplish going forward with you as our partners. This slide really needs no introduction. The title says it all.

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We live in a increasingly dangerous world in which threats to our national health security can arise anywhere at any time. Some of the threats that we are dealing with are here now, like COVID 19, multi-drug resistant bacteria and opioid overdoses. Others, like Ebola and nerve agents, have made themselves known repeatedly over the past several years.

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Still, others are further in our rearview mirror but are still visible like anthrax. Then there are the threats of nuclear and radiological weapons that we like to think hearken to another era, but are in fact being actively pursued in the Middle East and the Korean Peninsula. And the most insidious of all, these threats are the ones that have not yet made the presence known, the ones that are not even yet named the John Dose of national health security threats, the threat axis.

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Collectively, these range of threats for which BARDA, CBRN team has dedicated itself every day to countering. We in CBRN have a simple, well-defined and executable mission, which is to make available at least one medical countermeasure or MCM against each and every one of these threats. To accomplish this mission, we are pursuing a three pronged strategy develop medical countermeasures that treat the medical consequences of chemical, radiological and nuclear threats when the threat itself cannot be directly targeted or mitigated in an effective and timely manner.

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Number two: deliver medical countermeasures with novel mechanisms of action and improved concepts that directly target all bacterial and viral material threats. And bringing these two approaches together to deliver and develop broad acting and or threat agnostic capabilities effective against the future threat actors.

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And since 2012, we have we have made good on the strategy supporting the FDA approval, licensure and clearance of 24 medical countermeasure products that target many of these threats to national health security. In fact, just this past year alone, we have supported and overseen the approval of six products to our monoclonal antibody treatments for infections due to Ebola Zaire that have been used in multiple recent outbreaks in Africa. One is a new treatment with a novel mechanism of action against smallpox infections.

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And now there is a treatment for thrombocytopenia resulting from acute radiation exposure and to our interventions following the nuclear blast. One for the treatment of burn injuries and another for the detection of lung injuries. But getting these products across the finish line of FDA approval is not sufficient.

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We must also make sure that these products are available for use in the time of need. As such, we've invested significantly in the late-stage development, manufacturing and procurement of medical countermeasures that have addressed these threats using Project Bio-Shield or PBS funding. We have supported the advanced development of 30 MCMs and procured 20 products that can be rapidly deployed and used in the event of a public health emergency or mass casualty event. In fact, in just this past year alone, we have procured six MCMs for the treatment or prevention of such threats as Ebola, Zaire, smallpox and anthrax.

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With continued investment like this and with your help, we will continue to fulfill our promise to the American people to protect them from all threats to national health security. Previously mentioned, a primary effort of the CBN program is the repurposing of commercially available products and drugs and devices to be used in new ways as interventions against these severe and threats. To accomplish this, we have established the Redirect program, which is a collaborative effort between the Chemical Threat Medical Countermeasure Branch within CBRN and BARDA's Division of Research, Innovation and Ventures, or Drive that supports the

screening and identification of approved drugs that can be repurposed to treat the medical consequences following exposure to chemical threat agents.

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Under this program, we have made four awards in just the past six months alone. We've also advance the development of a variety of blood products to treat vascular injury, anemia and thrombocytopenia following acute radiation exposure, including the development of an innovative technology for on demand production of splay dry spray dried plasma. And we have expanded our thermal burns program to include the development of new diagnostics and treatment options for four traumatic blast injuries, while developing new tools to address the bottlenecks that occur during responses to mass casualty events.

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And while our efforts are focused on ensuring that we are prepared to respond to the medical consequences of all mass casualty events and public health emergencies, we are always ready to support the R and Asper with his response as soon as the call for volunteers went out in January 2020.

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The CBRN team stepped up to support and to lead many COVID 19 pandemic response efforts from leading the U.S. government's COVID 19 Medical Countermeasure Task Force to integrating into Operation Warp Speed and then the Countermeasures Acceleration Group. The efforts of every member of BARDA CBRN team have resulted in the development and delivery of multiple lifesaving vaccines, therapeutics and diagnostics to help the U.S. and the rest of the world overcome the COVID 19 pandemic. While everyone in severe and stepped up to expertly support the COVID 19 response, they continue to do their day jobs, which is to ensure that we are all well-prepared to respond to the severe on threats of today and tomorrow.

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As a result of their efforts, we executed nearly \$1 billion in funding, completed 80 contract actions, supported six FDA product approvals, delivered 13 products that are being used in routine care and participated in five outbreaks not called COVID 19.

To prepare for these threats of tomorrow, all branches within CBRN are launching programs that pave the way for a resilient future. A major part of that push is to emphasize the commonalities between the effects of chemical and radiological exposure and everyday conditions seen in emergency medicine in order to normalize and demystify the treatment of these injuries. To that end, our newly rebranded Burn Blast Medical Countermeasure Program has identified new core areas of investments in technology solutions like integration of

telemedicine and communications, and use of artificial intelligence and machine learning for detection of burn and blast injury and trauma.

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Treating the injury, not the threat agent, reflects the normal practice of emergency medicine, where the clinician treats what they see without the need for specific treatments tailored to the specific threats. A strategy that the chemical threat countermeasures program long ago adopted and continues to follow. Likewise, the Radiological and nuclear medical countermeasure program has identified key pathophysiology resulting from radiation exposure that have synergies and overlap with other areas like mechanical trauma, chemical injury and infectious diseases that allow us to leverage and coordinate it, coordinate our efforts across all of severe end in the development of threat agnostic MCMs.

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Working with our inner agency and international partners, we are supporting a robust preclinical and clinical development pipeline of novel antibacterial candidates that have the potential to address the most serious antimicrobial resistant infections identified by the CDC. Please keep an eye out for on our special, on our social media, for our announcement for the next generation of the combating antibiotic resistant bacteria. Biopharmaceutical Accelerator In addition, we will also be posting a new Project Bio-Shield request for proposals for an antibiotic to treat bio threats in AMR.

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With Ebola Zaire firmly in check through our development and delivery of multiple and effective vaccines and therapeutics, we have pivoted to the development of MCMS for the related viral of viruses, Ebola, Sudan and Marburg virus, which have caused sporadic outbreaks in Africa over the last 40 years.

To this end, we are leveraging the expertise platform technologies and lessons learned from Ebola Zaire Mscum development to underpin our efforts to develop new schemes for Ebola, Sudan and Marburg virus. We are also interested in investing in new technologies like demand and point of care, IMC, a manufacturing vaccine, patches and the needless delivery approaches that will provide us the enabling technologies to respond more efficiently, effectively and rapidly to the next outbreak or pandemic.

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And we are leveraging lessons learned from the COVID 19 response to develop creative ways to prepare for the Threat X outbreaks and pandemics of the future. To accomplish this, we are developing threat agnostic schemes like broad acting antivirals and host targeted system directed modalities, capable substantively reducing morbidity and mortality while threat

specific schemes are being developed. Depending on the product development, the development of these systems could be advanced to licensure for a known material threat while being evaluated as a threat to capability.

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Or it could be advanced through R&D filing and phase one clinical development, and then held for potential deployment through an EUA. If a public health emergency is declared, the bottom line is that severe and has taken a no holds barred approach to developing rapidly deployable and effective threat agnostic capabilities to respond to any future threat to public health security. As you can see, the CBRN team has been highly successful, delivering on its promise to the American people to develop effective arms to mitigate the risk of the most serious health security threats that face our nation.

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However, since the landscape of what constitutes a threat is constantly changing severe and is dedicated to preparing to address the next threat wherever it may emerge in multiple ways by leveraging the expertise of our personnel, the interagency and our private sector partners, severe end will develop pathogen agnostic and broad spectrum schemes with the potential to be efficacious against multiple virus species or families.

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We set an ambitious goal for preparing for new antibiotics by 2030, using Project BioShield funding through a new initiative called by four by 30. Through this program, we will revitalize the stockpile of antibiotics and expand our preparedness posture to address both bio threats and MDR bacteria, and to complicate our ability to respond to any severe end or pandemic event.

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To compliment the development of threat specific products, we will continue to develop host directed interventions that treat the injuries and symptoms following exposure to a threat agent rather than targeting the threat agent itself. Such project products have the potential to treat syndromic presentation even before the causative agent is identified, enabling a rapid and flexible response to a natural or intentionally caused events. Identification and rapid evaluation of MCMs is critical, but we also need ways to quickly produce, distribute and administer the MCM in question.

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Technologies that are amenable to on demand on site production are highly desirable to prepare us for the next pandemic. And finally, we will continue to engage with end users to establish a comprehensive burn and blast trauma care portfolio to better to provide better triage, detection and treatment options for our emergency care providers. To learn more about these and other initiatives within the CBRN portfolio, please check out these breakout sessions.

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Thanks a lot for your attention, and I look forward to meeting with you in the near future.