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- Hello, my name is Adam Clark. I'm a scientist in the CBRN vaccines branch at BARDA. And today I will be providing an overview of our branch activities and goals. It's been a busy year for BARDA with the development and distribution of multiple vaccines against the COVID-19 virus.

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And while we continue to stay focused on addressing the ongoing pandemic, it is important to remember that as an agency, we remain focused on a variety of threats. The vaccines branch has been successful in supporting licensure of Bavarian Nordic's MVA smallpox vaccine under the trade name, JYNNEOS.

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Merck's Ebola vaccine, ERVEBO and pre-emergency use authorization for Emergent BioSolutions, anthrax vaccine, AV7909.These vaccines will support our national strategy to make sure we're protected against these biological threats. However, there remain unmet needs for effective vaccines against other biological threats.

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This past summer, we witnessed potentially new threats emerging in the Marburg virus in Guinea that causes hemorrhagic fever and monkeypox appearing in an individual in the United States. In the case of monkeypox, we are fortunate that the smallpox vaccine, JYNNEOS, is also effective against monkeypox. However, the emergence of threats, such as Marburg virus, continue to reinforce the importance of BARDA's mission and the role that vaccines play in preparedness and response in the US and the world.

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While we have effective vaccines against diseases, such as smallpox, anthrax and Ebola, we continue to evaluate and support new vaccines that address unmet threats, or that may be improvements over current vaccines in characteristics such as stability, potency, or delivery. We have near term goals, including FDA submission for Bavarian Nordics, lyophilized MVA smallpox vaccine, Emergent's AV7909 vaccine against anthrax and Janssen's Ad26 Ebola vaccine. The lyophilized smallpox vaccine will provide years of increased stability to help sustain its availability.

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The anthrax vaccine AV7909 will provide a post-exposure prophylaxis that requires only two doses. This is an important improvement over the currently licensed three dose vaccine, BioThrax. In a post-exposure scenario in combination with antibiotics, the more rapid onset of protection will be critical to saving lives and may also reduce the duration needed for antibiotics in a post-exposure event. The licensure of Janssen's Adenovirus 26 prime MVA boost will provide much needed additional capacity for Ebola vaccines.

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As the Ebola, smallpox and anthrax programs have matured, they've transitioned into project BioShield. However, as they move toward licensed products, we are also looking to expand their utility for use in special populations, such as the elderly, pediatric populations, or immunocompromised individuals. In the development of these vaccines, BARTA values the concept of public private partnerships. Public health vaccines in the Sabin Vaccine Institute are new partnerships working with us to develop a much needed portfolio of vaccines against Marburg virus and Sudan Ebola virus. Merck, Bavarian Nordic, Janssen and Emergent have been instrumental in the public private partnerships that have helped us currently be prepared for other biological threats.

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We're now in a position in which we'd be able to use vaccines against Ebola, smallpox, or anthrax as part of a response effort, thanks to their teams. In addition, we have other numerous partners that are currently working on their areas of vaccine development through our nonclinical and clinical studies networks. These are complex programs and we couldn't get them done without our government partners in combination with industry. We work closely with the NIH, CDC, FDA, and DOD among others to ensure a robust pipeline of countermeasures that are suitable for advanced development and licensure.

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Our smallpox anthrax and Ebola programs are all maturing with either licensed products or products nearing licensure. Major near term goals are about getting these candidates across the finish line. We are targeting licensure for three products in the upcoming years, but in parallel, we really need to think about how to optimize these programs and generate additional data to support use of these vaccines. For example, non-clinical studies support clinical trials in healthy adults. However, it is difficult to extrapolate data from healthy animals for use in special populations. And while we sometimes look to expand the label of licensed vaccines to special populations, we also strive to generate data for pre-emergency use authorization in the event of an emergency.

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For example, we've been working closely with Merck on plans to expand the indication of the Ebola vaccine. The World Health Organization, going off recommendations from their strategic advisory group of experts, initiated vaccines in pediatric subjects and pregnant women. We engage heavily with our interagency partners to assess the current portfolios and where there may be areas in which these mature programs could be strengthened. For example, while AV7909 is expecting licensure for post-exposure prophylaxis for use in a civilian emergency with anthrax, generating data to expand licensure to general use prophylaxis for use by our military is a goal we are currently evaluating with our federal partners. Within the upcoming years, we plan on generating immunopotency data and clinical dose-ranging studies, including booster arms, that will better inform a clinical study to support licensure in the future.

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While we currently do not have open opportunities in our broad agency announcement for anthrax and smallpox, we plan to stay engaged with industry on new candidates for these threats. We're always open to hearing innovative solutions that improve characteristics, such as reduced number of doses for effectiveness, or enhanced stability profiles for the vaccine. Regarding Marburg and Sudan filovirus, our program goals continue to be to establish a pipeline of candidates and supportive models and assays to move through nonclinical and clinical studies.

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In one Sudan candidate that had at least demonstrated nonclinical efficacy in animal models of infection we continue to remain interested. In other novel candidates, they've at least demonstrated protection against a lethal challenge in non-human primates with a preference to any candidate that has moved into clinical studies. We are interested in platform type approaches where technologies may have been applied to other viral threats to see if those approaches could be extended to Marburg and Sudan.

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The expectation is that barring any major outbreak, the licensure of a Marburg or Sudan vaccine, would happen via the FDA Animal Rule. We're now working with multiple groups to establish animal challenge models to support this work. We know from West Africa and the Democratic Republic of the Congo that an available effective vaccine is a key part of the bigger response effort. While licensure of the candidates is the ultimate goal, we're pursuing clinical development of Marburg and Sudan candidates to get to the point where sufficient data are available that may support their use in an emergency.

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In terms of candidates, we're looking for monovalent vaccines that will protect us against these urgent viral threats. BARDA has also begun addressing antimicrobial resistant bacteria, or AMR, which are a growing threat to the public health of our nation and the world. While antibiotics remain steadfast countermeasures against AMR strains, it is possible for novel vaccines to play a role in addressing these threats in the years to come. While vaccines would help address primary AMR infections that may result from an injury, or complication from surgery, they would also be part of an overall strategy against secondary AMR bacterial infections resulting from any mass casualty event that may threaten our national safety and security.

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Vaccine-based approaches won't make sense for all, most urgent AMR threats, however, there are a subset of AMR threats, four of which are listed here, for which vaccine investments could make an impact. In previous years, working with NIAD, BARDA has already pursued early stage development of candidates through the CARB-X program, establishing public private partnerships to help push candidates through the preclinical development and into the clinic.

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For CBRN vaccines, we want to take it to the next step and work with industry partners to support early clinical stage programs and further de-risk these vaccines. We recently held workshops to hear from the vaccine community on the current state of affairs of AMR vaccine development. And there were key messages we learned from our interactions with that community. Namely, pipelines for these threats are limited, but they aren't non-existent. However, marketplace investments and the lack of effective animal models of disease for these vaccines remain challenges in earlier stage development.

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By de-risking earlier stage clinical development, the US government may be able to foster additional enthusiasm and investments from private industry to help address these threats. We saw tremendous work in the past years to accelerate clinical development of the ERVEBO Ebola vaccines. And 2020 witnessed Operation Warp Speed not only develop and distribute multiple COVID vaccines, but move the first mRNA vaccine into administration in the general public. This demonstrated there are still areas where we can see novel improvements in the vaccine landscape. In the upcoming years, we plan to look at novel strategies for vaccine manufacturing and administration.

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BARDA's DRIVe Division has opened up the Beyond the Needle program, which is seeking to support novel vaccine administration and delivery systems. In a panel that will present at this Industry Day, we'll explore the concept of on demand remote manufacturing of vaccines. As we witnessed from COVID, individual manufacturing sites can sometimes create a bottleneck in vaccine manufacture and distribution during a pandemic. However, with the advent of MRNA-based vaccines, it may one day be possible to synthetically produce and manufacture on demand vaccines at remote locations.

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While this concept is a bit far in the future, we will be exploring it and examining a potential role in moving it forward. Finally, none of this could be possible without a commitment of the numerous individuals in our programmatic and contracting offices who work collaboratively to ensure the success of the CBRN vaccines program. Their expertise and dedication to BARDA's mission continues to be a driving force to ensure our preparedness against biological threats.

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With this I will conclude this presentation and thank you all for listening.