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Good afternoon. Thank you for joining us today at BARDA Industry Day. I am Ruben Donis. I am the deputy director of the influenza Division, currently serving as acting director, while Dr. Robert Johnson is serving as CEO of the Countermeasures Acceleration Group for the COVID Response.

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So, I would like to now go to the next slide and start my presentation by recapping the accomplishments of FY 21. As you know, the division worked in overdrive and used all resources to support the COVID-19 pandemic response. The highlights of the pandemic response effort provide an important context for our strategy going forward.

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The chronology that you see on the screen start up with the first quarter in October of 2020 and going all the way to September 2021. Actually, a good way to illustrate how the COVID response actually informs our strategy for the influenza pandemic preparedness. Going forward in the first quarter of our partnership with many of the private sector partners actually achieved very important milestones in the pandemic coveted 19 response, Pfizer and modern advanced. They are covered mRNA vaccines to demonstrate 90% or over 90% efficacy in the phase three clinical trials and were eventually authorized by the FDA for emergency use authorization.

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Regeneron and Lilly, they developed monoclonal therapeutics that showed efficacy and were also authorized for emergency use. In addition, two of the COVID diagnostic tests were authorized by the FDA for emergency use. Moving on to the second quarter.

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By March of 2021, we had delivered 100 over 156,000,000 doses of vaccine. By then, Jansson had developed a corporate 19 vaccine that received authorization for emergency use by the FDA, and then two therapeutic monochronal antibodies were authorized, one for Genentech, which was the Tocilizumab and the Lilly Bam 80 combination. In addition, five diagnostic tests for COVID 19 were authorized by FDA in the second quarter. Similarly, important accomplishments in the third and fourth quarter, you see that the third quarter, more than 380,000,000 doses of vaccine were delivered, Pfizer received EUA for lower age indications, twelve to 15 years old populations and two additional diagnostics were and then in the last quarter, more than 171,000,000 doses of vaccine were delivered, one additional diagnostic, Pfizer got approval for the Ml vaccine and AstraZeneca received good response.

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Good data for efficacy on the phase three and then Regenerate also received approval for the expanded so these are important accomplishments that really set the stage for pandemic influencer preparing strategy going Forward this slide illustrates the major pillars of our pandemic preparedness strategy, starting with detection and then moving on to other aspects of prevention, treatment, and response.

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These accomplishments of the coveted response really are critical to inform our strategy going forward. The detection strategy really is not very different from what we have. None of these packages were really very different from what we had prior to the coveted response. In fact, the coveted response reinforced all the major elements of our pandemic preparedness strategy for influenza. In terms of detection, we wanted to bring diagnostics closer to the patient and scale up and expand production capacity.

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In terms of prevention. We wanted to improve vaccines, and we wanted to expand production capacity reinforced by the COVID response in the therapeutic area. We're wanted to develop novel targets with new mechanisms of action, and we wanted to have improved availability for hospitalized and for early stage in outpatient populations. Those were reinforced by also by the corporate response. So in terms of all of our strategy, we continue with the principles established before in terms of implementation for our pandemic strategy, we continue leveraging our public private partnerships with a really large array of collaborators in biotech and Pharma NGOs academic institutions.

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We have leveraged pre existing partnerships for the coveted response, and those partnerships were really critical rapidly pivoting and establishing development programs for products for medical countermeasures for the coveted response. Needless to say that in FY 21, as we think about the way forward for pandemic influenza, we will continue to implement our strategies through an array of public private partnerships. So the next slide really illustrates provides essentially a few examples that illustrate how the pre existing partnerships for development of influenza and other medical countermeasures within BARDA with the CBL and Division provided the platform from which we could launch very pivotal and launch very quickly development programs for COVID-19 medical countermeasures.

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So, you see in the middle row in Gray the products that several of our partners were either developing or had received authorization or even licensure for some of these products. Examples are the Regenerative monoclonal antibody there's a no fee flu block and the vaccine, the GSA and the Beckman Coulter Sepsis diagnostic tool.

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So those programs really show in the bottom row how those prior approvals led to quick and successful and very impactful medical countermeasures for the COVID-19 response, such as the vaccine by Johnson and Johnson, received authorization of the Moderna vaccine that received FDA authorization. Same for Regeneron monoclonal antibodies and the handheld COVID 19 diagnostic test from Q. And we are, you know, Sanofi and GSK are very close to getting the results of our phase three study for the recombinant adjuvanted COVID 19 vaccine. And the same is true for Beckman Colter with their multiple inflammatory syndrome diagnostic for COVID 19,so this just essentially illustrates hopefully how important it has been for us and for all of the government to have those previous products under partnership with Biden.

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So the acceleration of those products led to very important achievements in the therapeutic landscape. What we're showing here in this slide at the top, indicating that for all stages of the COVID 19 disease, we have developed a portfolio of products that cover all the different areas not only therapeutics as well includes the in the early stage in prevention through vaccines. So you can see that and on the so-called y axis, if you wish, you see that there are vaccines, immunomodulators and anti-viral therapies and the anti-viral therapies COVID cover in patients all the way from exposure to early symptomatic and to hospitalized stage.

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As well then the immunomodulators as you know they are useful in hospitalized patients with severe disease that requires oxygen supplementation or atmo.
And then the vaccines obviously are in the healthy prior to infection population and did all of these products were authorized? And in addition, the Pfizer product was subsequently approved by the FDA, and that's the mRNA vaccine. So clearly, all the early partnerships supported the rapid approval or authorization of vaccines and therapeutics for the COVID response.

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So I think that you can appreciate that this is really the cycle in which pandemic influenza allow the acceleration of the Pandemic influenza preparedness allowed the acceleration of the COVID response, and now the COVID response has really advanced the variety of products that will hopefully be informative and useful to improve our array of medical countermeasures for pandemic influenza preparedness, including and especially production capacity for vaccines, therapeutics and diagnostics.

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So in FY22, the division will invest in medical countermeasures that constitute the major pillars of our strategy, right? So therapeutics, vaccines and diagnostics, as you might expect. Zooming in a little bit into therapeutics development. In FY22, the division therapeutic strategy would focus on three priorities antivirals for outpatient use Antivirals that target the host and antivirals that are longer acting. And that's because we have clear gaps in the availability of influenza anti-virals to treat our patients. We need drugs that are effective and are more resilient to the emergence of resistant strains.

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We also need immunomodulators that can treat patients for more than five days after the onset of symptoms.

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And then we also need in the early stages of a pandemic the availability of long-acting antivirals that can protect people until vaccines become available. So this slide illustrates the new therapeutic the current yellow availability of medical countermeasures for influenza in the therapeutic space.

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And you can see that we have four drugs that are suitable for treating our patients, but we have nothing for our before infection or for hospitalized patients. So that's clearly the two gaps that are now being targeted for development. And then in the outpatient, we also seek the development drugs of new mechanisms of action that gives us options if resistant variants emerge.

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So I would point out that doctor Tim Armstrong will present that in greater detail the therapeutic strategy in the role as the lead of the Therapeutics Development branch of the influenza division OK, so in the next slide, I'm showing the emerging technologies that we intend to leverage for vaccine preparedness.

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So the vaccine's development branch and the pandemic Vaccine and stockpile branch are focusing on strategies that will enable a faster response, leveraging new technologies, faster pandemic response, I should say leveraging these new technologies primarily are trying to have vaccines that have a shorter interval from the identification of a new pandemic strain and the availability of product to immunize people.

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And in particular, the platforms, I think, are going to receive a lot of attention and many are related, you know, self amplifying, etc., etc. Those platforms that can go from sequence to vaccine very quickly are going to receive a lot of attention. In addition, we will emphasize the development of vaccines that could elicit protection with a single dose. So those regimens are going to be important.

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And also, vaccines that have improved can helps improve logistics, room temperature, stability and, most importantly, vaccines that can be administered without syringes and needles. We could use patches or oral vaccines or other alternative routes of administration that would be incredibly important. In addition, we will also emphasize the importance of making sure that vaccines are developed for all segments of the population.

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So as I mentioned previously for therapeutics, the details of the vaccine strategy of the division led by Dr. Jonathan Shields, who is the acting branch chief for the vaccine development branch and Christina of who is the chief of the vaccine preparedness branch, they will be presenting details in their talks later on today. So just to begin to wrap this presentation up, I should like I would like to mention that we are very, very interested, as I mentioned before, in the integration of new technologies into existing products.

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So that has been a particular challenge in the past, and we would certainly welcome proposals in which, for example, this year, as shown in the slide, we would like to see new alternative delivery methods,for example, for example, incorporated into existing vaccines and so on. Those require the integration of technologies from device in this case and microarray patches to device. And then you have the antigen and the holder of a license for a vaccine, and that requires a collaboration that we will likely to see emphasized to going forward the right tool.

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OK, so to close, I would like to again bring up the importance of not only integrating different technologies, but also integrating the different parts of our preparedness portfolio across the divisions of power. So as you know, the COVID response has really made our very self evident the importance of being prepared for emerging infectious diseases other than our traditional targets in the CBRN or in the pandemic influenza strategy.

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So as the name of our division points out, emerging infectious diseases is an important area and we are going to work proactively towards the establishment of a medical countermeasure portfolio for any emerging pathogen with pandemic potential. So therefore, in FY22 we will work towards sustainable approaches to achieving true preparedness, exploiting the synergies across the four segments of the BARDA portfolio. That would be an important objective of FY 22.

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So to close, I would like to again bring out the major pillars of our response and our strategy for pandemic preparedness, which is to essentially leverage faster platforms. That's going to be very important. Expand indications and access for medical countermeasures for pandemic, influenza and emerging infectious diseases, improve administration, including microneedle patches and alternative delivery technologies that expedite and facilitate distribution and deployment.

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And we are going to establish greater production capacity that is sustainable. And as always, continue to implement our strategies through Public private partnerships that leverage flexibility in our agreements to respond to the unknowns of the future. So thank you for your attention.