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Research!America Alliance Member Call with Dr Rick Bright and Scott Whitaker

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Date: April 15, 2020 Featuring: Dr. Rick Bright, Deputy Assistant Secretary for Preparedness and Response and Director of the Biomedical Advanced Research and Development Authority (BARDA); Scott Whitaker, President and CEO of AdvaMed Scott Whitaker discussed how the medical device and diagnostic sectors are working on to combat the pandemic. Dr. Rick Bright provided an update on BARDA's COVID-19 efforts.

Transcript
0:05
okay well i think we'll get started hello everyone it's jenny larae welcome
0:10
to today's research america alliance member call i think by now we're used to the
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mechanics of these calls but if you need a refresher uh we have a slide on the screen
0:22
and it explains that you need to mute how to mute and unmute your
0:27
line and also how to ask questions you type your questions in the question box
0:32
you can do that at any time and my colleague terry will be asking those
0:38
questions at the end and for those of you dialing in by phone will open up the phone lines after the
0:45
presentation and you can hit star six to unmute your line if you'd like to ask a question
0:51

so we are thrilled to have two terrific guest speakers today each of them will share how their
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organizations are working hard to battle coven 19. we flip the order at the last
1:03
minute due to schedule changes i'm really pleased to introduce scott whitaker our first
1:09
speaker he's the president and ceo of abamed prior to leading advamed he had various
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leadership roles at bio and also served as chief of staff and assistant secretary for legend
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affairs at hhs scott we look forward to hearing how the medical device and diagnostic
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sector has organized to combat the pandemic turning it over to you well very good
1:38
thank you jenny um and thank you to you and ellie and everyone at research america for all the great work that you
1:44
do not just in this issue but year round it's such a great organization and such
1:51
a strong entity and we're glad to be partners with you so i want to first of all thank
1:56
you for your leadership and partnership and your work as well so
2:01
so maybe i'll start just for those that aren't that familiar with advomed to give you a little bit of an overview of who we are and who we
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represent and then maybe lead in a conversation about what we're doing right now and then would welcome a q a
2:16
session after that so for those of you who don't know advent med well we represent the entire medical technology
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industry the traditional medical device makers but also the diagnostics companies
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as well and all the new emerging healthcare companies that are in the
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health technology space and so it's a very diverse set of companies that we have the good fortune
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of uh representing it's particularly interesting now because as we're fighting
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collectively as a nation and around the world the pandemic of uh globe of coven 19 our companies have been
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on the front lines of dealing with this sort of across all aspects of it so we have the diagnostic tools that are
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being used to diagnose the disease we have many of the medical equipment and supplies that are in hospitals to
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help treat the patients who are suffering from this disease and then most of our companies produce
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personal protective equipment of many varieties to help support and protect
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the nurses and doctors and health care workers that are on the front line the heroes on the front line of doing the work to take
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care of these patients and hospitals um and in other aspects throughout the communities that are
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impacted by it so we've had a front seat uh in this fight and you never want
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something like this to bring us all together but this fight certainly has brought this industry
3:43
together to help fight it so there are two aspects of what we do now that have been very very much front
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and center first is on the diagnostic side and i'll talk about that in a couple minutes
3:55
but first it was really on the personal protective equipment and the ventilator specific equipment that our companies
4:01
uh manufacture and so for those of you who and i'm sure most of you have watched the conversation the dialogue
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that has occurred there is a tremendous fear early on that there may not be even enough ventilators in the system to help
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manage the capacity issues that existed across across the u.s particularly in new york where the
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problem was very very acute so our companies were very deeply engaged with
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the federal government with fema with hhs and the white house task force to try to scale up the work we were doing
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to speed up the manufacturing primarily of ventilators but also personal protective equipment as well
4:40
just to give you a sense of the scale there and what we've done and what we're continuing to do
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in a typical week in a non-pandemic situation collectively this industry
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would manufacture between six and seven hundred ventilators per week to meet the regular demand uh inside the
4:58
hospital in the health care system in in the u.s but since cobot hit us we've
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had to scale up dramatically and as of last week we were somewhere between two and three thousand
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ventilators that the industry collectively was producing every week and then we're tracking up to about
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seven or eight thousand hopefully uh by the end of this month or early next month uh to continue to meet the
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demand the hope of course is that all of those ventilators we're manufacturing won't be
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necessary uh with the possibility remote though it may be that the disease regresses a little bit
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we don't have the onslaught that we anticipated but we're continuing to prepare as if
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the crisis is going to move across the country and scale up production of these ventilators there are two types of
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ventilators to oversimplify it there are those that are very very complicated in the
5:52
icu units that are used in critical care cases to help people who are really struggling with the disease those
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are really complicated and difficult to make i was on a television interview recently
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someone asked me how many component parts exist in those uh products there's about 15 to 1700
6:12
depending on the product so it's a pretty complicated machine and so scaling up manufacturing of that
6:17

has been a challenge for us there's also the non-invasive ventilators that are used outside of icu to help
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patients who are in the early stages or coming off an invasive ventilator and so our companies are
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are manufacturing and scaling up that as well you've seen some of the partnerships
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probably that we've had with car manufacturing companies ford gm tesla and others
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most of the work that they're doing is either to help us with component parts or to build the uh less invasive
6:48
machines and have them available as well to help with the healthcare need in the hospitals and so
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we've had a tremendous amount of focus on that over the course of the past few weeks
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and deep collaboration with the white house initially with hhs and then moving to fema
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when they started managing uh the response and then our primary work with fema
7:11
recently has been to help understand better the allocation schemes and how we can get the right ventilators
7:17
to the right locations to meet the need and so that's been a a huge focus for us and i i must admit
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though they're criticized oftentimes my uh my interactions with fema hhs fda and
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the task force have been very good and they're very responsive and it's been encouraging to most of our
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companies who have been in this space then the next thing that we've turned to is really on the diagnostic
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side and again where our companies are right on the front line of dealing with this challenge as you've heard from
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so many different people recently in order to get whether it's congress the white house or the media in general
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the sense is in order to get people back to work and reopen the economy there needs to be a certain level of testing that's

8:00
available to the average citizen and we're looking at that in two ways one is pcr
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testing or the front-end testing to determine whether or not you have coven 19 that you have a live virus in
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you that is already ongoing and we've scaled up dramatically on that side the next phase is really on
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the blood test for the serology test to understand who has had the disease and what level of immunity they have in
8:26
order to determine whether or not they can go back to work and if they're protected
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the work on the serology side is very active and ongoing in an aggressive way i was
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on a call with dr hahn the fda commissioner just about an hour ago we were talking through some of the issues and challenges we
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have on the regulatory side but there are two pieces of that that are really important from our perspective what our companies will do
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we'll manufacture the tests in order to make that determination
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but then you have the science of it the science scientists the doctors the government agencies
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that give you a better read as to whether or not certain level of immunity or exposure prevents the infection from
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reoccurring in folks and that's not work that our companies do directly but we'll be relying on others
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to do that so that's uh that's a focus of much of our work right now scaling up manufacturing on the front
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end the pcr test and then developing these new serology tests with hopefully a
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great degree of accuracy and efficacy to ensure that those tests are available broadly
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and then of course in the personal protective equipment area where our companies are doing so much
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work and we're getting tremendous support from other industries outside of just the traditional medical

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device and technology companies to make sure that there are enough masks and gowns and
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other necessary components and and to protect the doctors and physicians who are treating
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these patients an important level of workforce as well and the scale at which you have to
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increase that is just dramatic and we've seen that in new york where either you had shortages initially
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or they were concerned about shortages and you had to manufacture to such a tremendous scale
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the second part of that which has also been an interesting component that most people aren't aware of
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is making sure that those products are sterile when they go into the hospitals and then if you need to reuse to make
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sure there's a sterilization process in place to re-sterilize things when you need to go back in after a
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second uh for a second round of treatment in an emergency room or in a hospital more broadly and so
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a lot of work continues to be done there it was just announced last week we have a couple companies
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who uh created a uh a uh essentially a sterilization process
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for masks so that mass could be reused and which is a really important development and
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the ability to do that on a pretty massive scale is increasing as well so
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as i said at the outset you never want to have a crisis like that hit the country but i will say being a
11:07
part of the med tech industry it's been encouraging how well private sector and
11:12
the public sector have worked to create some solutions for the problem uh that we have um i uh
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it was mentioned earlier in a previous life i was at hhs and so i had a time as chief of staff
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there and we were on the front end of dealing with some of these 18 years ago

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and i've often said since that time as much as you would hope that the federal federal government
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would be fully prepared oftentimes oftentimes we're not fully prepared the question is how how do we respond
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and i think in this case uh the government's responded quite well uh some gaps but we've responded pretty well so
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with that jenny maybe i'll pause and open it up for any questions thanks scott that was terrific what a
11:56
great overview of what you and your members are doing terry do we have any questions
12:04
yes uh one question has come in scott you mentioned challenges on the regulatory side with
12:09
regards to the serology tests can you say a little bit more about what those are
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so there's two aspects of that one is making sure that we know understand the information that
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the fda needs to validate the quality of a product and so we're working on that with the
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fda right now and that has improved oftentimes doing it during a normal course it will take you months
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to get all that information straight and the good news is they're responding very quickly with the technical
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information they need to manufacture a test like this the other challenge we have we've had is
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to get samples from labs and from university research
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entities that we can use to validate the test and scale up the test and so
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that's not in any way a criticism of anyone it's just that when you're doing something new like this
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you have to have that type of collaboration and so that's one of the things we've
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been asking fda and the white house task force to work with us on is to help connect us
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with the research entities that are doing some of this have some of this basic information that
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we need access to and that coordination really helps us get a better more quality test and then
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scale up as quickly as we can so those are a couple of the issues that we have right now
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the other challenge we've had is exporting from china some of the tests that have been developed over there that's been a bit
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of a challenge for us and we're starting to see our way through that but there's not a clear path yet so that's been that's been
13:42
tough terrific um scott
13:49
terry i think we have some more questions we sure do um here's a question about mask sterilization does this best practices
13:56
use vaporous hydrogen peroxide yeah so there was some discussion around whether
14:03
or not we would use uh ethylene oxide which is traditionally used on the front end of most medical supplies when they
14:09
go into um the hospital setting and there's some controversy about what the what the best process would be but
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hydrogen peroxide is the standard that the new company it's not a new company but the new uh
14:21
new uh sterilization product uses and it it has shown to be very effective fda
14:27
has validated the effectiveness of it and so that's the focus of this uh this reuse or re-sterilization
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process great and i have a question here from our very own uh president and ceo mary
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wooley she says thanks for a great overview looking forward can you speculate on what the med tech industry and the
14:47
public sector have learned that will change the conduct and pace of innovation in the future
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so you know mary thanks for being on and thanks for your leadership and all you do i appreciate it um you know we've
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learned a lot i think it's a little too early to know exactly what we've learned one of the things we've learned i think
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that has been very beneficial is the emergency use authorization process at fda and the quality of that

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process and the speed at which fda can now move as a result of that and that has proven to be tremendously
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effective and gives our companies some comfort that they can go through a cup process and get a valid test or a valid
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product or scale up manufacturing in a way necessary to meet the demand the other
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thing i would say and this is not a criticism of any this administration the previous administration or anyone
15:42
else one of the things that i've recommended early on was that we do maybe a more aggressive job of
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stockpiling more particularly medical equipment so that in the event of another uh pandemic or another
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major public health need that we don't have to scale up as quickly at time right
16:02
and so that's been a bit of a challenge and i think we could probably collectively afterwards look back and
16:08
say had we known this is the level that we would we wish we would have had on hand
16:13
uh personal protective equipment of ventilators of other medical equipment and supplies as
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well and so i think that's a learning that all of us could benefit from going forward and then the last thing i would
16:25
say which is very general the importance of having uh confidence
16:30
uh from the public sector to the private sector from the private sector to the public sector that we can we can
16:37
partner together to find solutions it's not just the private sector doing it it's not just the public sector doing
16:43
it it's both of us and i think that collaboration has worked well and i think it's a really important
16:48
lesson for us all going forward terrific terry
16:56
we have additional questions oh yes definitely lots of questions coming in and thank you everyone for submitting

17:03
them again we'll try to get to as many as we can um can you talk a little more scott about efforts to reduce uh false
17:09
positive and false negative uh cover 19 diagnostic tests yeah so it's a great question and uh a
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lot of that is on the fda not to put a burden on them and again i think they've been fantastic
17:22
but setting a certain level of standard that we try to meet is important to ensure the validity of
17:30
the test or the efficacy of the test and they have said it uh at a reasonably high level
17:36
the tricky part of course is when you're in an emergency setting it's hard to get
17:42
to perfect and so there is ongoing concern of maybe higher than we had hoped false
17:49
positives but i think as we refine these tests uh they're going to get better over time
17:54
and i read something recently um just yeah i think it was yesterday i think it was dr falchi who said
18:00
even if you even if you think you have it and you test negative you should assume for a period of time
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given the outbreak that you might have it and then behave accordingly because there's things we can all do to
18:13
prevent the spread as a result of it so while there's always a risk of high or
18:18
low false positives if you're in that situation then you
18:24
need to behave as if you have it go back for another test or two and see as we scale up the number that are available
18:32
great and actually building on that question um what are you seeing in terms of labs um increasing capacity to process the
18:38
increase in test i'm not sure if this would affect is directly related but yeah yeah it's it's it's related and it's a
18:44
great question so i think one of the challenges we have is on on our end uh we manufacture
18:50
the test the test kits and the machines that run the test the high throughput machines and the you

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know lower volume machines as well when we finish that process we send it out to
19:03
labs research entities and to hospitals and they're the ones that actually run the
19:08
test and collect the data and so one of the things we're working on right now is to better understand
19:13
where are the capacity problems and where are their capacity opportunities and can we relocate some of that the
19:21
testing machine in order to meet the demand that exists right now and i don't have a good answer for
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you today but we've been engaged with the labs in those conversations and we've been
19:32
engaged with the white house uh and other federal agencies on that as well and we're all trying to better
19:37
understand uh where the opportunities are to scale up
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because as you know in some areas we're just uh inundated with requests in other
19:48
areas the demand is not nearly as high
19:55
great thank you so much another question here can you say a bit more about your work with fema regarding distribution of
20:01
ppe yeah so that that's been a really tough challenge for us but i think
20:07
overall they've done a very good job i think it's both in ppe and also in the ventilator space both
20:12
um in the normal course we would fill orders that come in from customers and
20:17
send those directly to the hospital the health system whatever it might be and get them what
20:24
they need based on our capacity that we have and then when we scale up we'd scale up and send as well
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the challenge to this crisis has been that a a company like those that are members of
20:36
our organization don't necessarily know all of the hot spots right and so the orders come in
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and everything seems like a hot spot and so essentially what we've tried to do with fema

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is to coordinate those activities in basically a 50 50 system so we'll fill part of our orders using
20:55
ventilators as an example and then we'd get direction from them on the other half of our orders as well as
21:01
we're scaling up so they can send either we'll send to the stockpile or send directly at their
21:06
direction to the locations that that need these machines or the ppe so it's been a blended effort i think
21:13
one of the things we both agreed upon early is we didn't want to ship them all to the stockpile and then
21:19
have the stockpile ship them all to the locations that it would slow things down and so that's why we've landed on this
21:24
blended blended effort and we've made good progress in that the demand is on the pp on the basic ppi east side is
21:32
uh is so dramatic that it's been honestly it's been a challenge but in their defense i think they've
21:37
done a done a good job or as good as they could under the circumstances
21:44
i think i'm gonna step in with a question scott um you know you talked about all the
21:50
different components in ventilators and um i know that's also the case in in diagnostics um there was
21:58
some talk of by american executive order and i just wondered um where that stood
22:05
and and your perspective on that and you know how that might impact um the work that you're doing right now
22:13
yeah another great question we had a lot of uh conversation about that and some
22:18
concerns um about that i think you know we when we communicated uh with
22:23
the administration i understand the point that they're trying to make as we've said to them though a number of
22:29
times now is probably not the best time to try to implement that um because whether we
22:35

like it or don't like it whether we think the system is good or bad the reality is that the supply chain is
22:41
distributed all over the world right now and if we restrict access it's going to
22:47
cause other countries to do the same thing we didn't want to have that type of backlash which would really
22:52
impact our ability to import into this country many of the component parts that we need also ppe and um and so we we've had
23:00
quite a back and forth on that and i i feel like uh based on my latest conversations that's
23:07
the concept is still in play at some point but it's not urgently in play and i think they've set
23:13
it aside until the until this crisis passes at least i hope that's the case and then
23:18
once we get to the end of it we can come back and have a conversation about how we can manufacture more
23:24
in the united states and what it would take to scale up to do that which is a fair question but it's
23:29
certainly not a policy change that we would recommend at this stage okay very good um we have a few more
23:36
minutes so i think we can see if anyone who has called in by phone has a question so
23:44
just to remind you you uh pressed r6 to ask your question
23:58
all right well hearing none scott this was just terrific we really appreciate your time and we
24:05
look forward to continuing to work with you and your wonderful team
24:11
good luck and let us know how you know research america and our
24:16
alliance members can help you um in any way absolutely you've been great partners and we will
24:22
be in touch mary thank you for being a part of this ellie jenny the whole crew we appreciate all your work thank you
24:29
terrific thanks so much scott well terrific
24:36
and i believe that um dr bright is has joined us now
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um and you know it's really a wonderful segue because scott
24:48
talked uh about the importance of public and private sector cooperation
24:54
and dr bright is right in the middle of that um as the deputy assistant secretary for
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preparedness and response at hhs and the director of barda the biomedical
25:07
advanced research and development authority uh dr bright actually began his career
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in vaccine and therapeutics development at the cdc and also has extensive experience in the
25:19
biotech industry dr bright we are so pleased that you could join us today um and we look forward to hearing from
25:26
you about what bart is doing in the covid 19 response
25:31
and i believe you have some slides to share with us i do i have slides thank you everyone i
25:38
wanted to see the slides come up and we're going to add to the technical difficulty i've
25:43
actually had the opportunity to speak in several virtual conferences over the last few weeks and with mixed results when it
25:50
comes to slides so we'll see if this works but i uh while you're setting that up i really wanted to spend the time to thank
25:56
everyone um thank um mary wool in particular for all of the correspondence that we have on an
26:02
ongoing basis to stay in touch and the entire research america alliance for
26:08
everything that you're doing um not only in the middle of this response right now or maybe we're still beginning at the
26:14
response actually many many areas um but throughout um even in non-response times to
26:20
ensure uh the collaboration and the visibility and important communication about
26:26
our research development enterprise and our scientific enterprise to be able to develop critical life-saving
26:33
medicines and vaccines and diagnostics so we can protect america and protect the world um
26:40

from events such as we're encountering now but also everyday threats that we face ambarda i'm going
26:46
to go to the next slide for those who don't know barda you know we're a component of the
26:52
assistant secretary for preparedness response the asper in the department in the
26:57
secretary's office actually of health and human services in asperger we live by one mission and
27:04
that is to save lives and protect americans from 21st century health security threats
27:09
we know that these threats are many and we know that they are increasing not only in number but
27:17
intensity around the world ranging from uh when we started anthrax uh threats
27:23
that we face with anthrax but also nuclear proliferation and and um plague
27:30
and and um tularemia and smallpox and pandemic influenza so a number of
27:36
chemical and biological radiological nuclear events and and then these emerging infectious
27:42
diseases such as ebola and sars and now this coronavirus so
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those are an example of the various threats that we tackle each day in a very strategic way
27:54
to be able to work with private sector merging with the public sector as scott
28:01
was saying the need for that to develop the drugs and vaccines and diagnostics to prepare
28:07
our country and treat americans when we're exposed to these the next slide barta is the biomedical
28:13
advanced research and development authority and we have a unique mission we were set
28:18
up with a very unique mission and that is to intentionally bridge public and private
28:24
the government and private sector industry in a unique public private model
28:29
to be able to accelerate medical countermeasures with drugs vaccines and diagnostics
28:35
that would be usable for many of these threats we face and uniquely many of those threats that
28:41
we tackle require very unique medical countermeasures

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so there isn't an established marketplace for many of those countermeasures and therefore not only do we support
28:53
companies to accelerate the development of that medical countermeasure both financially and also by providing
29:01
technical expertise we also manage project bioshield
29:06
which is a very unique mechanism that allows us to procure some of those materials
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those drugs and vaccines and diagnostics in late stage development and create a
29:18
marketplace a pseudo marketplace for those things that don't have an ability to sustain a
29:24
marketplace out in the in the market in the regular public marketplace people are not lining
29:30
up to buy a smallpox vaccine or an anthrax treatment right now so we do
29:36
need to make sure that those companies that make those life-saving medicines and treatments
29:41
are there when and when we when and where we need more of those materials if we are exposed to some of those threats on our
29:49
next slide it just shows a snapshot of the number of companies we've worked with we're
29:54
only 13 years old and in those 13 years we have worked with now over 300 companies
30:02
small large multinational some of those tied into academic institutions of all
30:08
sizes to be able to identify a solution to many of these threats to identify a path forward to accelerate
30:16
the approval and usability of those medical countermeasures on the next slide it also goes without
30:22
saying how critical it is that we work across government and make sure that we're partnering with all of the
30:29
critical partners in government that are either enabling us or accelerating or
30:36
collaborating with us in some way in these public-private partnerships to accelerate the development of the
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medical accounting measure nih and cdc and fda are absolutely integral and critical to our
30:50
success in accelerating and making available these drugs and vaccines and diagnostics
30:56
the next slide shows it's just if i can just you know for one moment just highlight the success without
31:02
appearing to be bragging but you know over the 13 years we've been in existence
31:08
through our public and private partnerships through industry and collaboration across
31:14
government this model has yielded 54 new fda approvals licensures and
31:21
clearance or clearances for everything ranging from influenza pandemic influenza vaccines to
31:27
ebola vaccines and diagnostics and and therapeutics and chemical medical countermeasures
31:33
smallpox anthrax a full range for burn products etc of medical countermeasures that have
31:40
gone over the finish line so they can be used some of these in everyday life
31:46
to be able to sustain those for when they're needed for an emergency response and some of these are in the strategic
31:52
national stockpile and procured or acquired so we have those on hand to meet an emergency need
32:00
when it arises that being said on the next slide as we think about the response in the
32:07
middle of response right now for coronavirus it's called 19 disease it's critical to
32:13
emphasize the need for speed speed is the most critical component of
32:18
a response because even though we have many of those or any of those
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accounting measures that maybe have fda approval or maybe in late stage development or
32:29
maybe even a strategic national stockpile or maybe they're in the marketplace
32:34
they are not help at all and they fail unless they are present in sufficient
32:40
quantities when and where they're needed so we have to think about each of these
32:46

components and operational aspects to make sure we have the capability to surge scale and distribute
32:54
when you need um to do so in an emergency response even when you have a satisfactory
33:00
medical countermeasure already on the shelf so in the next slide is um one of the mindsets that we are
33:09
thinking about in barda when we stood up a new division of research innovation adventures in
33:15
2018 and i think uh mary wooley asked a question to scott a few minutes ago
33:20
about innovation and where we bring innovation into this whole system you know as we're seeing now in as we
33:27
look at new drugs and new vaccines and new diagnostics in the in the middle of this response
33:33
you know the critical need to rethink our development and evaluation and
33:39
production and distribution processes end to end to make sure that we are
33:46
not wasting any time making sure that we are thinking strategically and in new ways to be able to make the
33:52
countermeasures available as quickly as possible we have begun evaluating and in this response we are
34:00
actually implementing many new strategies to make the medical
34:05
accounting measures available or get data from medical county majors as quickly as possible
34:10
and that is only done in collaboration as scott mentioned to the excellent work that the fda has
34:18
been doing in this response and working with industry partners of all sizes
34:23
to be able to move as quickly as possible and rethink or revise
34:30
even some particular strategies if they potentially slowed down a process the
34:36
entire time keeping safety first and forefront of everyone's mind as we move aggressively to ensure we're
34:44
not doing anything bureaucratically that would slow down the potential availability or evaluation
34:50

of a life-saving drug or diagnostic or vaccine in this outbreak
34:55
so in this slide it just talks about the various areas either a situational awareness this is the diagnostic or
35:01
testing or the test to characterize whether a person is infected or has already been affected and may be
35:08
immune and able to re-enter the workforce to how quickly we design a new vaccine
35:14
or a drug and manufacture and validate those validation as you'll see as we get more and more into
35:21
the drug development the vaccine development a lot of innovation even in the clinical trial
35:28
design and regulatory review that we all have to put in place to move as quickly as possible
35:34
manufacturing will be done in very unique um collaborative ways and and as scott was
35:40
talking in his his overview a minute ago talking about the public sector and the private
35:46
sector and how public and private sector are working more closely in this outbreak it's also really
35:52
gratifying to see how industry partners are collaborating and teaming in unique
35:59
ways that i've never seen in my many years in this business putting profit aside in many cases
36:05
putting competition aside in many cases to bring together the best capabilities to work
36:11
together to to truly have one focus and mission and that is to end this pandemic as quickly
36:16
as possible the next slide nine i don't think anyone on the telephone needs to be on the call
36:22
needs to be reminded but this is our third coronavirus outbreak in 16 years and
36:28
none of them have um been really mild outbreaks i mean they have all shown to be able to cause significant
36:35
disease and and and death in people and in spite of that in spite of the
36:40
surge of attention during an outbreak and the weighing of that attention after it appears to go away
36:46
we still don't have any um fda approved clear to licensed products to be able to

36:52
detect or protect or or treat someone with a coronavirus infection so we are adamant this time
37:00
in this outbreak to bring everything to bear to finish the job this time to ensure
37:06
that we have drugs and vaccines and diagnostics that are approved by the fda for use not only through this outbreak
37:13
but for also future coronavirus outbreaks slide 10 tells us how how tells you how we're getting there in
37:20
in government so it's not an isolated response within government i think it's really important
37:26
that everyone understands that we are working very collaboratively within the
37:32
government partnerships and communication within hhs and all of our agencies
37:37
along with usda homeland security department of defense and every agency or department that could
37:43
contribute to the successful acceleration availability of a medical countermeasure as you can
37:50
imagine we're getting a lot of interest in a lot of information from private
37:55
sector and in academic sectors and so it is because of this close collaboration with this
38:00
interdepartmental interagency group task force we have that we're able to align and prioritize
38:07
many of those um those interesting submissions that we're getting some of
38:13
them very interesting some of them we know quite well some of those are really novel and we're open to all ideas as you're on
38:20
the line and think about communicating with us we've also tried to make it very simple
38:26
for you to reach all of these agencies with a single email and that is a submission to a special
38:32
portal we set up at medicalcountermeasures.gov so if you have a concept of technology and idea
38:38
and approach if you submit it there instead of sending it to one of the many email boxes you might
38:44
reach into then it's guaranteed in that portal that you'll have interagency

38:50
access and be able to look at that review that in a very systematic and collaborative way the
38:56
next slide slide 11 shows the various agency-wide engagement we've had with
39:01
industry and developers and academic community a number of engagement calls we
39:07
some of you have been known barda in the past know about our tech watch programs we have modified that to a coronal watch
39:13
program and so we can communicate and tell the developers our priorities and our
39:21
process at the same time they're able to tell us and share with us what they're developing and how and why they think it
39:27
would be instrumental in the outbreak and where it is in development
39:32
the next slide shows you a snapshot of the activity in this area i won't
39:38
walk through each of these areas i hope you can get the slides afterwards but to show that we've had
39:44
over 2 000 submissions into the portal already i think as uh this is as of the
39:51
13th so two days ago um about different submissions into that
39:57
portal for about two to 300 submissions coming in each day at this point lots of ideas
40:04
and as those ideas and submissions are reviewed by the interagency task force then they are ranked
40:12
and then triaged for a tech watch call or corona watch call and we've had over 204 of those specific
40:20
calls with developers to learn more about their technologies it will be absolutely impossible to get
40:26
through all 2200 of those and that is why they are actually working together to triage those
40:33
in different areas and also very quickly to send some of those out to
40:38
various funding opportunities are already on the street either barda broad agency
40:45
announcement a number of nih open solicitations homeland security darpa dod cdc

40:53
so wherever those are out there if we see a submission come in that we know would fit squarely into one
40:59
of the solicitations we try to communicate that to the offer as quickly as possible
41:05
so we don't have much daylight between that submission and getting connected with the potential funder
41:12
on the next slide slide 13 just a high level snapshot of the strategy that we are using in barta
41:20
to focus on the highest priority medical county measures for this response
41:26
we want to accelerate development as much as possible to do so we are looking at
41:32
platform-based technologies and and that's a often loosely used term we say platform
41:38
technology we are indicating a vaccine platform or a drug or a monoclonal antibody
41:45
platform that has already been approved or licensed or cleared by the fda if
41:51
it's a diagnostic platform that the fda has already cleared in the past it saves
41:57
a lot of time to add another um pathogen onto some of those platform technologies compared to building an
42:04
entirely new diagnostic technology from scratch or drug or vaccine
42:09
so we're looking for those technologies that have been approved by the fda or have been in late stage clinical
42:15
development if it's a vaccine that's been in tens of thousands of people around the world for other
42:21
other pathogens or other targets then there's going to be a lot of experience in that facility there's going to be a
42:28
lot of experience in safety data file likely on on file fda and so we'll be able to move
42:34
more quickly with some of those technologies we're looking to repurpose licensed products as much as possible
42:40
and we're also looking to conduct parallel activities and says sequential activities
42:45

i'll tell you more about that in the next slide mitigating risk we understand this is high risk that go
42:51
faster we have to go faster therefore it's important that we're willing to accept
42:56
more risk if that's financial risk and investing more in technologies and domestic manufacturing and scale up
43:03
and scale out at earlier stage than we might normally do in normal vaccine or drug development
43:09
then we have to be able to understand those risks take some of those risks and monitor
43:15
them closely and manage them as as we go through the development cycle domestic manufacturing is also
43:22
absolutely critical i heard a question just a few minutes ago in the discussion
43:28
about some of the requirements or discussions about domestic production and investment in medical
43:34
countermeasures i think it goes without saying and as we've seen in previous outbreaks as we're seeing in this outbreak too
43:42
that many countries with capabilities are already restricting access to or
43:48
export of those capabilities or drugs or api or vaccines we saw
43:54
a restriction of vaccine distribution in the 2009 h1n1 pandemic as well
44:01
so it's really important to be able to keep that in mind as we invest at risk
44:07
and scaling up and scaling out that we are to every extent possible ensuring that we're building that
44:14
capacity and that capability in the united states so as we invest american taxpayer dollars in particular
44:21
into this capacity building and capability that we will have an ability to ensure
44:27
that americans have access to those drugs and vaccines as they become become available i think
44:33
it's unreasonable at this point that think other countries would share until they have already fulfilled their
44:39

own domestic needs so it's our challenge and our commitment to make sure that we are thinking first too as we invest that
44:47
americans will have access to the drugs and vaccines that they are investing in for this response
44:53
on the next slide just a quick example illustration this is an illustrative slide
44:59
to show how we're thinking in terms of compressing a timeline for development of a new drug or a new vaccine
45:07
traditionally you would develop a nice preclinical model and and perhaps a very small gmp
45:15
or g not even gmp sometimes batch that you can start some early in vitro data and analyzing your immune
45:22
response or selection of your early drug candidates
45:27
and then you would make a small bit larger batch and go to an animal model maybe a bit larger batch and go
45:32
into phase one and you would stop and go and stop and go and this pathway could take you anywhere
45:37
from eight to ten years to develop a new drug or vaccine in this response because of the
45:45
experience with many of the manufacturers the platform technologies because of the close communication and and flexibility in
45:52
many cases and with the fda and because of the whole of government approach where we're
45:59
bringing all the expertise from across hhs agencies onto each project
46:04
then we're able to look at ways to compress these timelines to have many different
46:10
activities going on in parallel while we're monitoring for any signals
46:15
that would ask uh that would you know inform us on whether or not we should pull back or divert or bring a different candidate
46:22
into the into the front line here so it is one of those things i described the previous slide
46:28
an at-risk approach it does cost more to do this however the outcome if successful
46:36

would be tremendously rewarding if we could have a drug or vaccine available sooner and that is why i stayed on this
46:43
the big red box that this is an olive government and an all a private sector collaborative
46:49
approach to be able to work together in an unprecedented way to develop these drugs and vaccines as
46:55
quickly as possible on the next slide slide 15 i'll go into
47:00
each of the high level thought processes strategies for the diagnostics and therapeutics and
47:06
vaccines and then i'll show you our current portfolio that we built and barda
47:11
for the diagnostics you just had a very nice extensive discussion on diagnostics
47:16
but to give you an overview of how we've been looking at our investments and diagnostics from barda
47:22
up to now we were focused initially on supporting and accelerating those
47:28
molecular based diagnostics that were laboratory based so we can put into the commercial
47:34
marketplace those capabilities with a high throughput instrumentation with a lot of experience in a proven
47:40
platform that we can add another test to another lane to whatever it might be
47:46
to be able to detect for the antigen the coronavirus or the sarge kobe 2 antigen on those
47:54
that would allow us to determine acute infection in individuals understanding the still limitations
48:02
of a laboratory only based or large laboratory public health laboratory based diagnostic
48:08
we also very rapidly started investing in point-of-care molecular diagnostics and
48:14
point-of-care antigen diagnostics things that are moving closer and closer to the patient so away from
48:21
expanding from a centralized laboratory into those commercial laboratories
48:26
into the hospital laboratories into the doctor's offices the urgent care centers and beyond
48:32

because we wanted to close the timeline the gap from taking a specimen from an individual to getting
48:38
that result as quickly as possible for their health care provider to inform
48:44
treatment or social distancing or iso or quarantine or whatever the appropriate
48:49
activity needs to be in the third circle in this slide a huge
48:54
effort now is ongoing to develop and validate the various
49:00
serology based or antibody based diagnostic tests it's critical to be able to know if a
49:08
person has already been exposed to the virus and know if they have antibiotics to that virus especially the
49:15
right kind of antibodies and the antibodies a sufficient level to inform them of their protective
49:21
status comfort that individuals will seek to be able to return to the workforce and
49:28
return to society and i believe get our country back to work and back on track in addition
49:35
the last box we're not only submitting supporting developers of diagnostics in each of
49:40
these areas we're also working very aggressively to get the samples get the specimens
49:46
curate those specimens put them in the repository at the nih or cdc and make those panels
49:52
and make those reagents available to the developers so they can validate their own tests and
49:58
and diagnostics and move that technology forward as quickly as possible on slide 16 next slide
50:04
therapeutics it's basically approach as i mentioned already to move
50:11
as quickly as possible we are participating with a number of companies a number of international
50:17
organizations to screen every possible drug out there that could
50:22
impact or react or neutralize or treat a person with this infection with this virus so
50:29
we really are focusing on repurposing fda approved drugs and getting as much
50:35
information about those as possible there's a lot of interesting information

50:40
i see an email every day and reading the news every day in the global media about potential for any for many
50:48
different drugs or treatments or approaches to work and we are working as swiftly as possible to
50:55
get that information and put those therapeutics those drugs into a randomized controlled study
51:02
in a very um stringent way with a placebo control or the most appropriate control so we
51:09
can have the best information possible to inform health care workers
51:14
and and actually the world on the benefit or concerns about each of those drugs
51:21
that we're learning about each day when it comes to developing a new therapeutic
51:26
we're looking at two different approaches some of those are targeting the host the blocking
51:33
the virus activation or blocking or counteracting inflammatory response or
51:39
cytokine storms so things that might modulate that host response
51:44
and things that target the virus itself so very specific antiviral drugs that
51:50
might target the viral replication pathway or monoclonal antibodies or polyclonal
51:55
or convalescent anesthesia and a convalescent plasma that would
52:00
target the virus and neutralize it if we have those things that target the virus then
52:06
we can also explore both treatment modalities for those drugs
52:11
as well as perhaps prophylactic use of some of those approaches to provide a prophylactic treatment that
52:19
might bridge up and provide protection for frontline workers in critical workforce
52:24
until we have a vaccine the next slide is a little more depth on the repurposing
52:30
of the vaccine i don't think of the therapeutics i don't think i need to go into too much detail on it we're working with a number
52:37
of entities private entities companies academic labs and tied in with centers at gates
52:45

foundation and global efforts as well to screen the drugs starting with those approved
52:51
drugs looking for hits looking at those in phase three clinical development looking at those in phase
52:56
two and phase one and hoping that we can find as many options as possible as late stage development as possible so
53:04
it doesn't take as much time and effort to be able to find something that works
53:09
when we find something that works and might work we're very rapidly moving into clinical
53:14
evaluation we showed that we can do that with our partners in industry and fda and nih in particular
53:23
with a matter of weeks and max when the news came out about the potential for
53:28
ielts six receptor molecular antibodies to have a positive impact on the inflammatory process seen
53:35
in many of cova 19 patients in advanced stage illness we actually moved swiftly with two
53:43
companies with regeneron and with genentech to get clinical studies up and running
53:48
randomized controlled studies to evaluate the impact of those monoclonal antibodies in clinic
53:54
and then of course the challenge as we find positive encouraging data making the right decision on when to
54:01
scale up production ensuring that there's enough capacity if we find a drug that works
54:06
the worst thing that not have it worse than not having a drug that works and having anyone that works and very limited supply and we already
54:14
have seen some examples of the consequences of having
54:19
drugs with promise or hope and then a very limited access to those or manufacturing
54:24
capacity or limited supply chain so we're trying to stay one or two or three or four steps ahead of the
54:31
data to know where we should pull triggers to expand and invest in increased capacity at the
54:36
same time the next slide is on vaccines and in vaccines again this is a very um

54:46
how would i say it's a very active area of development so there are probably 65
54:52
or 70 or maybe 80 different vaccine candidates approaches that i'm learning about from around the world
54:58
academic centers from small biotechs from large pharmaceutical companies and it is a particular challenge to
55:07
evaluate so many candidates in a very systematic way to understand
55:13
which of those have the most promise or or ability or potential
55:20
to move forward quickly with sufficient supply with sufficient capacity with sufficient data and a
55:28
regulatory pathway to move into clinical studies and then have large-scale quantities of those
55:34
as early as possible so we have tried to triage many of those candidates with a
55:39
few principles and again there's there's never a perfect way to evaluate so many
55:47
promising candidates and so we're trying to focus first on those that we think
55:52
would move swiftly and second on those that would are from a proven platform so if
55:58
it's a licensed vaccine it's going to give us a lot more clarity
56:03
on a regulatory pathway if it's a licensed platform it's going to most likely have existing capacity infrastructure
56:11
to manufacture and scale up a lot of experience from a a group or a company that is knows how to scale
56:18
a vaccine quickly and in some cases it's going to have global reach so it's going to be a technology or platform
56:25
that's licensed and proven and likely and able to be more easily transferred
56:31
to multiple manufacturing sites globally so we can think about a global scale up and
56:37
production approach for the vaccines in addition to what we need to make domestically and we also in the last
56:44
circle never want to forget about innovation so there are some truly remarkable

56:50
innovative vaccine approaches and systems and and new platforms uh arising and some of those we've
56:57
tracked for decades some of those we've learned about in the last few weeks to be honest with you and
57:05
really interesting technology and some really promising attributes and so along the entire
57:11
pathway of trying to triage and prioritize we are looking at innovation as well
57:16
because it's sometimes not the first vaccine to the clinic that would have them it's also not always the most
57:24
proven or stale or vaccine that has the most promise sometimes is where that innovation comes
57:30
in that can make a difference in a rapid response for a pandemic and that innovation could be as simply as an
57:36
alternate delivery administration method if i have a vaccine i can deliver orally
57:41
that's going to reduce the burden that will for needles and syringes it's going to be able to be administered
57:48
more quickly in some other way those types of innovation are things we're also looking at and considering
57:54
as we look at the many different vaccine candidates the the last slide on the technology
58:01
slide 19 again goes into more details i think i highlighted this and i talked about our
58:06
earlier principles for accelerating our overall medical countermeasure approach but particularly in vaccines
58:14
talked about the ways that we are looking to accelerate development as much as possible using platform technologies repurposed
58:22
or licensed technologies and looking at those parallel activities in the middle
58:27
mitigating risk there's the risk of yield low yield mitigating the risk
58:33
of you know scalability the risk of lessons learned from other
58:40
approaches and vaccine development and in particular some early vaccine development for the

58:45
first stars outbreak with the potential for some of those vaccine candidates to
58:51
have signs of disease enhancement we have to be fully aware of those and monitor for that
58:56
test for that and mitigate for that if that's what we're seeing alternate routes to delivery the concept
59:03
of redundancy is absolutely critical um with the outbreak that we're seeing with the type
59:09
of buyers we're seeing we have to think about um the people who go into the facilities as
59:16
well and protecting securing the people and knowing that
59:21
no one facility is going to be sufficient to make the full number of doses we're going to need in our country or globally
59:28
so we need to have redundancy and produce that vaccine in multiple facilities at once
59:34
and also if we have individuals or people who are have to drop out of the workforce because of getting
59:41
infected themselves or getting sick or taking care of loved ones or family members we have to make sure that we are
59:47
thinking in a redundant manner to ensure that we still have constant steady flow and meeting an
59:54
aggressive timeline to have vaccine available and the very last column there is about
59:59
the domestic venue manufacturing one of the things i'll highlight in that area is the need to think about the raw
1:00:06
material supply chain there's just not enough stainless steel
1:00:12
on the planet right now to make enough needles to administer vaccine to the world
1:00:17
uh there's very limited supplies that borrow silica sand and tubing to make enough vials
1:00:24
and so we have to think strategically and aggressively up front at risk on how we will ramp
1:00:31
up those supply chains how we move from a thought of a single dose vial to multi-dose files and
1:00:37
different types of strategies to try to address the constraints on the supply chain that we know we're going to hit

1:00:45
as we need vaccine as quickly as possible slide 20 shows our landscape or our
1:00:50
portfolio so far so you can see we've invested in a number of therapeutic approaches that
1:00:56
meet each of those principles and and tears that i discussed in the previous slide
1:01:02
through convalesce theorem and plasma hyperimmune serum monoclonal antibodies
1:01:08
and an antiviral small molecule drugs vaccine candidates a number of diagnostics in each of those
1:01:14
areas a number of supporting efforts that we have in place to accelerate animal models and sample
1:01:21
collection slide 21 don't want to close without acknowled acknowledging the um 200 people is what
1:01:29
we have in barda that is working that are all working day and night with that single mission to
1:01:35
to save lives and and move this pandemic out of our future into the past as
1:01:41
quickly as possible contract officers technical people working with our company partners hand
1:01:46
in hand every day and on slide 22 the final slide
1:01:52
this is how to reach us so i know that you all are working with companies or know of
1:01:58
companies or ideas and solutions i encourage you to respond to this call out to submit their
1:02:06
information into our portal medicalcountermeasure.gov look at the broad agency announcements
1:02:12
that we have already on the street and see if there's a technology that you have or know of that would fit into one
1:02:18
of those categories and submit your information to us as quickly as possible
1:02:24
i will stop there and hope i have left some time for some questions thank you all well dr bright that was
1:02:31
really terrific you and your colleagues are certainly firing on all pistons at barda
1:02:37

that's for sure um we have passed the 2 30 mark but if you have a few extra minutes we do have some questions
1:02:44
that have come in can you stay with us for a couple more minutes yes absolutely all right thank you terrific
1:02:51
um well i have a question um in terms of people who have not submitted
1:02:56
to barda before or who um have less experience any tips that you
1:03:03
can share you're getting such a high volume of applications um what should people know to make it
1:03:10
easiest for them to convey what they're trying to do that's a great question um and instead
1:03:17
of if you have a technology if you've never worked with barda in the past i really do recommend submitting an
1:03:24
inquiry or an abstract or a slide deck or a summary whatever you can into that
1:03:30
medicalcountermeasure.gov portal that is a conversation it's not a formal submission of a white paper
1:03:36
or proposal but it is a submission of your ideas and our subject matter
1:03:41
experts and program officers and across government will arrange a call with you
1:03:47
or reach out for more information and in that conversation they will be able to give you some
1:03:53
really clear guidance on whether or not your technology is something that they're looking for it fits into
1:03:59
any of the areas of interest and which agency would be the best agency for you to submit to
1:04:05
that might be depending on your stage of development gives you an opportunity to pressure
1:04:10
test some of your concepts or strategies you'd like to present to us so then when you
1:04:16
and and that is all market research on both sides your side and our side
1:04:21
and then if you decide and and it's clear that you have something to submit into one of our solicitations
1:04:29
either through white paper proposal you have a much better idea and so when you submit that

1:04:34
it should make the process go much more quickly it shouldn't be uh here's what i think and then i
1:04:40
we have to sit back and know that's not what we're looking for in a very technical bureaucratic process
1:04:46
if you leverage that upfront conversation effectively then you should have a real clear idea
1:04:52
on what to submit and it should move much faster
1:04:57
thank you dr bright uh terry do you have one or two questions that have come out i sure do yes i do uh
1:05:03
thank you so much dr brian i have one question here what are barda's priorities with the funds it is receiving via the
1:05:09
cares 3 act we are extremely grateful for the funds um from the care
1:05:15
act we've received funds in the first supplemental um we received funds
1:05:20
in this in this next one the carriage iii act and uh extremely grateful for congress and
1:05:25
for having that confidence in us and our track record to work with industry
1:05:30
we are prioritizing the things that really are discussed today how to find the the vaccines that need
1:05:37
to be accelerated how to identify the best drugs and get clinical studies moving as
1:05:44
quickly as possible so we can identify those best hits and how to find
1:05:50
and scale up the availability of diagnostic and testing to as quickly as possible this seems like a lot of money um in
1:05:58
that number so it's a big number however as i described the the parallel approach
1:06:05
and the risks that we have to assume up front that is why um it is incumbent upon us
1:06:11
to find ways to accelerate with that type of funding to accelerate our manufacturing
1:06:19
scale up redundancy for large-scale production of the drugs and therapy the drugs and vaccines and so with that
1:06:27

we're able to unlike in the past talk with companies and be able to
1:06:33
discuss a full development pathway instead of an incremental pathway one of the challenges we've had
1:06:39
in the past especially with pandemic outbreaks or these novel emerging pathogen outbreaks yes
1:06:46
sometimes it's very difficult to find a private sector partner to work with us
1:06:51
it is not clear to them that we would have the funding to support full development of that drug or vaccine
1:06:58
with the sufficient funding that's been given to us so far we're able to give more confidence to those industry
1:07:04
partners that we're going to be able to fully fund and take a product to the finish line
1:07:09
and not have to walk away if the disease wanes we really have with the support of
1:07:14
congress with the funding with our industry partners a goal now to finish the job and get a
1:07:21
coronavirus vaccine and drug and diagnostic approved by the fda
1:07:27
wonderful thanks so much and i have one more question here from our very own mary wooley she adds a wonderful amazing
1:07:33
work by barda thank you and your colleagues i've heard that approvals of clinical trials for covid19 therapeutics are over
1:07:40
texting irbs might it be possible for barto to set up a covet 19 specific irb to speed
1:07:45
things up you know mary i hope you're out there and can hear us i really appreciate
1:07:50
again as i said beginning your collaboration and communication throughout all of this your leadership
1:07:56
is just amazing that is a really good question and that is something that we are talking about
1:08:02
with our nih and fda and cdc colleagues as well as we think about the various
1:08:08
therapeutics coming in and i wouldn't say that we were naive going into this but certainly has been eye-opening going
1:08:15

into this the number of different potential drugs and therapeutics that could be
1:08:22
considered or that need to be evaluated and the way to streamline those evaluations um to
1:08:28
those those different clinical trials to be able to look at many of them at once instead of one by one by one by
1:08:35
one by one is critical so we're looking at those tools like a streamlined
1:08:41
clinical study with multiple arms of data clinical style trials wedge step designs perhaps for
1:08:48
evaluating vaccines and enrolling additional candidates or for therapeutics many of those lessons learned from the
1:08:54
ebola outbreak are things we're evaluating now you'll see that government via nih
1:09:02
and fda and cdc and asper and barda are really forming a new union
1:09:09
in a way that we really have talked about and have attempted and done parts of in the past but you'll really
1:09:15
see us starting to fuse in an unprecedented way to be able to work with the private sector now
1:09:22
to find these ways to streamline evaluation of drugs and vaccines and that
1:09:27
approach that you mentioned there your streamlined irb and clinical trial design is something
1:09:32
absolutely in discussion terrific well thank you again dr bright
1:09:39
that was a terrific presentation and we know how precious your time is especially right now so thank you again
1:09:46
i'm going to turn to a few quick announcements and thank you to our alliance members who
1:09:52
are staying past the um formal end time of this call we hope you can
1:09:58
join us for our next alliance member call on monday which is at 2 p.m
1:10:03
with dr harvey feinberg president of the gordon and betty marth moore foundation and chair of the
1:10:10
national academy standing committee on emerging infectious diseases among many uh areas of expertise he's an
1:10:18

expert on the policy landscape around vaccines and then on wednesday we have a
1:10:23
special webinar panel understanding the landscape of cobin 19 vaccine
1:10:29
and treatment r d with dr mark mcclellan dr julie gerberting and dr stefano
1:10:35
bertuzzi so we look forward to having you join us next week as well
1:10:40
thank you again and stay in touch
1:10:46
thank you