

OWS Background Briefing

July 30, 2020

3:00 pm EDT

Coordinator:

Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. During the Q and A session, if you'd like to ask a question, you may press Star 1 on your phone. Today's call is being recorded. If you have any objections, please disconnect at this time. Now I'd like to turn the call over to Mr. Michael Caputo, Assistant Secretary for Public Affairs. Sir, you may begin.

Michael Caputo:

Good afternoon, everyone. Thank you all for joining today's background briefing call with senior administration officials to discuss Operation Warp Speed. In just a minute, I'm going to turn it over to two administration officials that will be delivering today's background briefing.

On the call today is [Senior administration official], and [Senior administration official]. [Senior administration official] and [Senior administration official] will both make opening statements after which we will open the call up for on-topic questions.

All statements or answers to questions on today's call will be on background, attributable to a senior administration official. When asking a question, please state your name and publication and please keep your questions as short as possible so that we can get to as many questions as possible. We look forward to sharing as much information with you as we can when we can and in a timely fashion as part of our commitment to transparency at Operation Warp

Speed.

As I'm sure you can appreciate, there are a number of factors that affect our ability to share information, including securities laws, considerations around market-moving information, and our need to take precautions that prudent developers of innovative products take all the time.

If there are questions that we are unable to answer today because they could touch on one of those guardrails, we are happy to work with you on this if and when such information can be shared. Again, as a reminder, any statement or comments by [Senior administration official] or [Senior administration official] are on background only, attributable to a senior administration official, and with that, I'll turn it over to [Senior administration official].

[Senior administration official]:

Okay, welcome, everyone, and for those of you who joined us -- I think around July 13 -- it's great to have another opportunity to brief you. It's been a very productive couple of weeks since then. Just by way of reminder, Operation Warp Speed is dealing with not only vaccines, but often overlooked therapeutics, so we're going to say a few words about therapeutics and the developments there as well today. And then also, kind of a third vertical in Operation Warp Speed is diagnostics, but that's largely being run by Dr. Tromberg, Dr. Collins, and our colleagues out at the NIH.

So an exciting week for Operation Warp Speed. I think probably all of you read about the two Phase 3 clinical trials that began on Monday. One, of course, was Moderna -- which began Monday morning -- and then Pfizer BioNTech Phase 3 clinical trial began on Monday afternoon. Without revealing a lot of numbers, there were several hundred folks who got vaccinated on day one in the last couple of days, so we feel we're off to a great

start there.

We also recently signed a **contract with Pfizer**. It's an **advanced purchase agreement**. It was **\$1.95 billion for 100 million doses** and I think the **interesting part of this contract was we only pay for the doses should they achieve approval** on an Emergency Use Authorization or licensure from the FDA. So that's a nice way of saying they put themselves at risk, not the US government and its taxpayer and we feel very good about that contract.

Also, you probably read this morning that **Janssen -- Johnson & Johnson's subsidiary developing a vaccine** -- announced its success in primates and I think also exciting about that is they talked about achieving that success with a single dose.

We have also -- as you know -- **invested in Oxford AstraZeneca**. Their trials around the world continue. **They will begin Phase 3 clinical trials we anticipate here in the next couple of weeks**, so that will be imminent as well.

And then of course, Novavax, which is a protein-based vaccine who is contracted out as manufacturing to Fuji. I think you probably read the President visited there just earlier this week and that is going extremely well.

We mentioned this before -- the door is not closed on vaccine candidates. We have **three criteria** for investing in vaccines. One is there **early evidence of promise** for that vaccine from a clinical perspective? Second, given the timing of what is required to get through Phase 3 human clinical trials, **is it possible for them to do that somewhere before the end of 2020 or early into 2021?** And is it also feasible that if those trials are successful, that we can have **tens of millions of doses already manufactured at the same time**.

So there may be and you may have heard of **some great vaccine candidates that will be hitting the market in January of 2022**. Operation Warp Speed is **not interested in investing in those**. We have a very firm set of guidances from the President of the United States, which is deliver vaccines to the American people by year-end or early 2021. So those are the ones we're investing in.

A little bit just about therapeutics. Many of you saw the - probably the media guide today, but the President is over at the American Red Cross talking about convalescent plasma, as you know. The Mayo Clinic is under an expanded access program and they are collaborating with us. There are somewhere north of 40,000 Americans who have had doses of convalescent plasma for COVID-19.

We are in the process of evaluating those data to understand the correlation between different titer levels and the impact on the patient. Certainly, we're enthusiastic about its potential, but more to come there. The President today is talking about encouraging Americans to donate plasma -- those who have recovered from COVID-19 -- to help fellow Americans. Again, you'll hear more about that today.

Then there is remdesivir you've heard a lot about. We are shipping remdesivir every week based on need and demand in certain parts of the country between the first of July and the end of September. There are approximately 500,000 courses of treatment for Americans that the federal government is helping to direct to the right place. Again -- at least anecdotally -- what we're hearing about remdesivir is that given early in the course of treatment, it's having a substantial positive impact. We'll need to confirm that, but we're enthusiastic about that.

And then there's the monoclonal antibodies. Regeneron you've heard we've

invested in and we anticipate in conjunction with the NIH -- companies like Regeneron, Lilly, AstraZeneca in particular -- to announce, you know, over the next couple of weeks, a series of clinical trials that will subscribe to a common protocol overseen by the NIH.

If those are successful, we can anticipate significant volumes of therapeutics hitting the market this fall, let's call it between the middle of September and the first of November. So these will likely precede the vaccines and the availability of vaccines, which will come a little bit later in the fall.

So to summarize, in the last couple of weeks, our enthusiasm has grown significantly based on trial results, based on the initiation of new trials, based on just the growing at least anecdotal evidence about the impact these therapeutics are having on patients -- both of the key therapeutics that I talked about -- and we believe we're entirely on track with what we anticipated in terms of where we'd be at this point in time. So I'll hand it over to [Senior administration official] who'll give you a little bit -- Oh I'm sorry.

Michael Caputo:

That's okay. This is Michael Caputo. I just want - I know some people have joined a little late. I want to remind you that on the call today is [Senior administration official], who just spoke -- I'm sorry to interrupt, [Senior administration official], and [Senior administration official]. [Senior administration official] and [Senior administration official] are both going to be on background, their comments attributable to a senior administration official. I'd like to turn it over now to [Senior administration official].

[Senior administration official]:

Great. Well, thank you again for your time and we certainly appreciate the dialogue. The key message from me is that I represent a large team and our

large team is working relentlessly and deliberately to deliver substantial quantities of a safe and effective vaccine to Americans. We could not be working harder and we will continue to do so until we accomplish this mission and it is a profound mission focus that is appropriate to the response that is needed for this awful pandemic.

Now, I plan to cover a few key topics today. The first is **how we are accelerating vaccine development timelines without compromising safety and efficacy**. The second is **how we're working to ensure that this vaccine is distributed**. And the third is a little bit of a status update in addition to what you heard from [Senior administration official] in the vaccine candidates that we're supporting.

So first on our timeline, we're looking at every way possible to accelerate the vaccine development process. We've brought together what I can truly say is the best of what the US government has to offer along with the private sector in partnership to achieve our mission.

Just within the United States government, we work hourly -- a large team that I lead with the National Institute of Health, the CDC, HHS BARDA, the Department of Defense, including DARPA -- and we really want to dispel this notion that we are somehow separate than all of this expertise in the United States government.

We are all one big team and I can truly say that I've worked in the government. I was an active duty infectious diseases physician on these issues for decades and I've never seen a more cohesive, unified, inner agency effort to address this issue.

Last time we spoke, we highlighted in detail how Moderna accelerated the

vaccine discovery process at an unprecedented pace. We're very excited. We're very proud to see this Moderna product now in a Phase 3 clinical trial and it's important to highlight that that Moderna product was developed in such close coordination with the National Institute of Health and the vaccine research center. All of that led to what we think is going to be a safe and effective vaccine.

Another way we're speeding up the research and development process is through harmonization both in our process and looking at our clinical outcomes. The opportunity that we have in Operation Warp Speed is to work with multiple candidates and what we can do is in these candidates, we can look for common clinical endpoints, standard assays to measure vaccine activities, and common approaches with clinical trial protocols to enable transparency, but also to enable this apples to apples comparison across candidates.

Typically, each company develops their own vaccine candidate and has their own approaches. This - we get that apples to apples comparison and it will really allow us over the period of years to see which vaccines may work best or may be safest in different populations.

It is the - and again, this is the advantage of investing in multiple vaccines and again, we remain optimistic that not one, but many vaccines will ultimately be safe and effective to address this pandemic. The standardized approach also allows us to have a standardized common regulatory pathway while the FDA will still maintain their independence and of course, their high standards.

Another thing I'd like to address -- which we didn't talk about much last time - is manufacturing. I think everyone appreciates - it's extremely challenging and it's extremely complex when you get into the biological variability of

basic materials, how you scale antigens. We always remind people, too, that the FDA will approve a vaccine, but they also have to approve that manufacturing process.

We want to make sure that what is manufactured is safe to be given to people. There's common equipment sometimes, but there's also specifics on the vaccines and the fill-finish process is extremely complex. I bring up all these details because we are deeply engaged in every single one of those details and every single step of the process to look for where we can expedite, but still maintain the quality of that finished process.

The other advantage that we have is that we benefit in this from the synergistic teamwork in logistics, in operational planning, in program management between the Department of Defense and Health and Human Services. We're constantly looking for where there may be risk or potential delays and we're addressing them accordingly.

The second topic -- again very briefly -- is on vaccine accessibility. We understand this is an incredibly important and challenging process and we rely on the characteristics of each vaccine and the recommendations of highly qualified experts and organizations to inform this approach. It's very hard to anticipate while we're still learning about the safety and efficacy of these vaccines in terms of when and where they will be distributed.

However, we can do quite a bit of contingency planning and that's what we do. But the key point of emphasis is that we are informed by very appropriate processes. One example is the Advisory Committee on Immunization Practices. Another excellent example is an initiative led by Dr. Francis Collins at the National Institute of Health that he's working with the National Academy of Medicine, focused on ensuring the equitable allocation of

COVID-19 vaccines.

This group does soliciting perspectives from the public, from bioethicists as well as true subject matter experts in vaccines. And we look forward to them and us providing that information when these working groups have delivered their recommendations.

As I previously described, our current focus is moving as quickly as possible, but the key point is that we need to thoroughly evaluate how well these vaccines work across the different populations. And when there's multiple candidates, this is going to require a nuanced approach and the point for you today is that as we do these clinical trials, what we want to do is deeply understand how well they work in populations that may be most vulnerable to the complications of these infections.

Finally, just to briefly highlight what [Senior administration official] said, but to elaborate that it's important to remember that these vaccines that we are investing in -- examples include AstraZeneca, Pfizer, and Moderna -- have already been publishing their data from some of their early clinical trials and we feel like these results are really promising in terms of their immune response to COVID-19 infection.

Why do we say this, is that we see the antibody responses that have occurred, but we also can compare those antibody responses to naturally occurring infection and in these cases, those responses are at least equivalent -- and sometimes even better -- than the immune response from naturally occurring infections.

We've heard Dr. Fauci talk about this with the Moderna vaccine specifically, but it also applies to the AstraZeneca and Pfizer products. So when we use

this phrase -- cautiously optimistic -- it's not just pure speculation, it's based on data.

Finally, I want to - a key point really I feel strongly compelled that I hope you can communicate to the public is how appreciative we are of the literally thousands of volunteers that are participating in these clinical trials to evaluate these vaccines, as well as the thousands of professionals who are using their expertise, working day and night to run these clinical trials so that we can have - we can understand how these vaccines work and ultimately have a vaccine to address this pandemic sooner. Thank you very much.

Michael Caputo:

Okay, with that, we'd like to take some questions.

Coordinator:

Alright, the phone lines are now open for questions. If you would like to ask a question over the phone, please press Star 1 and record your name. If you'd like to withdraw your question, press Star 2. First question is from Liz Szabo with Kaiser Health News. Your line is now open.

Liz Szabo:

Hi. These vaccines are really impressive technologically, but distribution could be just as big of a challenge, and we have had problems with distribution in the past with test kits and with PPE and ventilators. Can you tell me some details about what you think's the biggest challenges for distribution will be and how you plan to overcome them to make sure there aren't shortfalls and make sure the vaccines get to where they're needed most?

Michael Caputo:

Great question.

[Senior administration official]:

It's [Senior administration official]. Thank you for your question and let me answer it directly. What is the biggest challenge, I think your question was. It's the uncertainty and what I mean by uncertainty is we have to plan for a multitude of scenarios. Will the vaccine be effective in certain parts of the population and not effective in other parts of the population?

What volume will we have at what period in time? Will we have simultaneous vaccines that we have to deal with? So, there is - will it be one dose or two doses? Some vaccines are one dose, some vaccines are two doses. The cold storage conditions under which we have to transport and store them are different by vaccine.

So when you do the number of combinations of all of those variables, you have a lot of complexity. We believe we are planning for all of them and there's a number of components associated with planning for all of them. One that will be pretty standard across the board involves information technology.

So from the factory, from the manufacturing facility through the distributor warehouses to the point of administration and post-administration, we are going to keep track of every individual in the country who's getting this. We have to do that for a number of reasons, as you can imagine. One is many of these are two dose vaccines, so we need to make sure that the individual who gets the first vaccine, first of all, comes back for the second one.

But more important, gets the appropriate dose when they come back from the same manufacturer. That's important and then of course, there's what they call Phase 4 kind of trial information, which is following persons for adverse events and clinical outcomes and those types of things.

So there's a huge IT component. We will be leveraging a lot of private partners who already have a good deal of that in place. We are under negotiation with several of them, but suffice it to say, we are not developing all that from scratch.

Second, there's actually the logistics of this and I mentioned -- I alluded to it -- different storage conditions, different transport conditions. Early on, we're likely - I mean, we're not going to wait until 100 million doses are produced before we start administering.

So let's say we get 5 or 10 million doses, we have to be very careful about how we distribute that not only in terms of who -- as individuals should be our priorities, which [Senior administration official] can talk about -- but as important, you can't have 1,000 distribution points if you only have 1 million doses. We have to be very deliberate about the number of places because we don't want to spread our inventory out too broadly when we don't have enough to support folks. So we're going through all that.

And then third is indeed administration itself. So there's IT, there's the logistics, there's administration, and this is going to be unlike the influenza vaccine where it's largely a pull system -- meaning, oh you know, a CVS or a Walmart says, "Send us 1,000 doses of this," and then we wait for the next order to come in. We are going to be pushing the vaccines out hopefully to nursing homes, to seniors who are not ambulatory and stuck in their homes, to frontline healthcare workers, to meat packing plants, name it.

And you know, again, we're still setting those priorities of using -- and [Senior administration official] can talk about that -- but this is going to be a push system where we are delivering a lot of vaccines and not waiting for the

orders to come in. So all of that's under consideration, but the biggest challenge by far is the uncertainty which creates a great number of scenarios, which creates complexity. [Senior administration official]?

[Senior administration official]:

Nothing further to add except for that. But I would say for anyone who's served in the military or known someone that does, I really think we excel at operational planning and I think the key way to address uncertainty is plan every detail with every contingency. And I think - I hope that, frankly, the American public can be reassured that, you know, I don't see how we could work details more than we have been to address all of those different contingencies based on vaccine, as well as we learn, you know, which vaccine works best for which type of person.

Coordinator:

Next question is from Sarah Karlin-Smith from Pink Sheet. Your line is now open. And Sarah, if you're there, please check your mute button.

Sarah Karlin-Smith:

Hello? Hi.

Coordinator:

We can hear you.

Sarah Karlin-Smith:

Can you talk more about the standardized common regulatory pathway that you said all the Operation Warp Speed vaccines will go through? What does that actually mean in terms of the FDA process?

[Senior administration official]:

Yeah, so this is [Senior administration official], and yeah, very good question. So the FDA has published guidance publicly available for COVID-19 vaccines and so, again, we repeatedly emphasized that, you know, we are accelerating where we can accelerate, but that we are not cutting corners. And so these vaccines will follow that pathway that the FDA has publicly said, "This is the pathway to follow."

What we also, though, the point of harmonization is that what we've done is for the companies and the vaccines where we are funding their clinical trials, we've encouraged them to have common endpoints, and what that means is if someone gets sick with COVID-19, then we describe that -- we collect the same information from each of those patients -- so across the different clinical trials, you're collecting information the same way.

The other part is that we're getting samples from the people that receive vaccine and comparing those samples with the exact same assay. And I know that sounds a little bit wonky, but the point is that allows you to say whether it's vaccine A or vaccine B, we measured the response in the exact same way and that it allows us to say, "Oh, they're about the same," or that one is better and one is worse.

Coordinator:

Next question is from Jon Cohen with Science Magazine. Your line is now open.

Jon Cohen:

Hi. Thanks for doing this and for taking my questions. I had a quick procedural question and then I had a scientific question. Procedurally, given the commitment to transparency, why do you insist on doing these on background as opposed to us quoting government officials by name? And my

scientific question is there's a lot of concern about the election interfering with decisions and pushing forward a vaccine.

And building off the last question, the procedure typically is the FDA goes through the vaccines and relay to Biological Products Advisory Committee to discuss results from trials. **Is there a commitment to have the Advisory Committee evaluate any EUA requests and it's not specified in the FDA document you mentioned about COVID-19 vaccines?**

Michael Caputo:

Hi. This is Michael Caputo, Jon. On the off the record, on the record question, you'll remember last time we did this, the Janet Woodcock was on the record. These decisions are made cross-departmental between HHS and DOD and what the person, their status - on the record status is determined by their department.

So you will see some people on the record, others off, and those are decided case by case by their department. And I'm going to turn it over to answer the rest of your question to [Senior administration official].

[Senior administration official]:

So, it's a very good question and it's an important one. In terms of, you know, how do we engage and how do we follow the regulatory process -- whether that is to Emergency Use Authorization or that's to licensure -- and again, I know this sounds overly simplistic, but we're following the process every step of the way so that the - and that process is very well known. It's the FDA engagement, the FDA approvals, the FDA - when you get your investigational new drug and process, you submit appropriately.

All of those steps are being followed -- how we design the clinical trials, has

the FDA reviewed that process, how do you ensure safety through those clinical trials? Each of the clinical trials that we're funding are following those standard processes. And so again -- we say this a lot -- but I hope that is reassuring, frankly, that we're not going to cut any corners and that if these vaccines are safe and effective, then the regulatory approval process goes appropriately.

Coordinator:

Next question is from Sarah Ower Mohle from Politico. Your line is now open.

Sarah Ower Mohle:

Hi. Thank you for taking my question. This is along the lines of some of the stuff discussed in the first distribution question. I was wondering if specifically, CDC would be running the distribution and the allotment as with most governments as it has in the past with flu vaccines and outbreaks or whether it would be the Department of Defense or if it's going to be a totally new sort of leadership structure led by Warp Speed and (unintelligible) now?

[Senior administration official]:

Yes Sarah, it's [Senior administration official] here just addressing your question. The answer is it's a joint venture between the two. So [Senior administration official] and I were just in again in a meeting this morning on distribution. And it is a combination and there's different roles for each. And I'm being very simplistic but the DOD is handling all the logistics of getting the vaccines to the right place at the right time and the right condition.

Things like postvaccination, tracking of patients will be handled as you could expect by the CDC. Some of the communications through the state and the state relationships the state public health organizations will be handled through the CDC.

So we believe we've actually combined the best of both where the CDC will do where if it has a comparative advantage dealing with the states tracking patients or, you know, those who are vaccinated thereafter whereupon we're calling upon the resources of the department, the great vast resources of the Department of Defense to help us with all the logistics.

And it's not just the logistics of distribution it is the logistics of manufacturing and the logistics of preparing for manufacturing as well. And it involves things like kitting, kitting, K-I-T-T-I-N-G. So, you know, we're in receipt and we'll continue to be in receipt of hundreds of millions of needles, and syringes and vials.

And all of those need to be prepared properly by type of vaccine. The DOD is handling all of those logistics. That's where their comparative advantages and the CDC some of their IT systems relationships with the states and following postvaccination will belong to them.

Coordinator:

Next question is from Lena Sun with the Washington Post. Your line is now open.

Lena Sun:

Thank you. Thank you for doing this. And could I just follow-up with [Senior administration official] on that. So the CDC has an existing public health infrastructure where they coordinate getting the vaccine, central distribution, send it out to providers who can sort of log into the system that's what they did in 2009.

So I just want to make sure I understand you are not going to be using that

existing public health infrastructure that is all going to be handled by DOD. And does that mean then the states don't have to purchase vials, or syringes, or wipes are all the things that have to be done when you give somebody a shot?

[Senior administration official]:

So on the former no it's going to be a hybrid. It's going to be a hybrid. We are indeed there's a number of very specific applications the CDC has for tracking vaccinations, for getting information from the states. We're going to use that and more. On top of that we will have some integrators who are helping us bring together both the CDC IT capabilities as well as some new applications that were going to need that the CDC never had. So it's a combination of that.

And we're going to call upon the private market to help us the distributors have IT systems, the retailers who will be helping us have IT systems. Again is going to be a hybrid including the best of all. But the CDC infrastructure will be a part of what we are leveraging. I'm sorry what's the second question? You had a, there was a second part of the question I didn't write it down.

Michael Caputo:

Lena, can you repeat the second part?

[Senior administration official]:

I think it was - will the states have to purchase...

[Senior administration official]:

Oh right, right, right we are on track, and we said this publicly before, we are on track to have over a billion needles, syringes delivered and tens of millions of vials, hundreds of millions of vials. We've made those investments in both expanding capacity for the broader market and for actually receiving those.

Why would we ever order a billion because we have vaccines that have different needle gauge requirements and different syringe size requirements and some of them are multiple doses.

So we are going to be preparing those kits and we are going to be distributing those kits along with the vaccines. To the extent that the states decide they want to purchase vaccines on their own then they'll be on their own for the needles and syringes but we are prepared to deliver those along with the vaccines through the distribution channels we described which include the state public health agencies.

[Senior administration official]:

If I could...

Coordinator:

The next question...

[Senior administration official]:

...this is [Senior administration official]. And if I could just add again, I know we've said this four or five times. I think it's a really important message that there is not an Operation Warp Speed team, and a CDC team, and one other team we are one United States government, we are one team.

We will take the best of any of the distribution options that are out there and we are informed on a daily basis as a larger team from the CDC from state and local public health to accomplish this mission. So I hope we can after this sort of dispel the notion that we're somehow different, we're one team.

Coordinator:

Next question is from John Wilkerson with Inside Health Policy. Your line is

now open.

John Wilkerson:

Yes on the Pfizer vaccine does HHS plan to pay the same price for the next 500 million doses of Pfizer's vaccine as it did for the first 100 million?

[Senior administration official]:

Well so this is [Senior administration official]. As you know it's an option for us to. So we have made no firm commitment to buy an additional 500 million. We've made a commitment to buy the first 100 million. If we have three or four of our vaccine candidates delivering 100 million or 200 million doses each we're not going to be buying more and we'll just have to see. So we've made no commitment in terms of the additional 500 million or at what price. What we've done is created an option for us to acquire those.

Coordinator:

Next question is from Sharon LaFraniere from the New York Times. Your line is now open.

Sharon LaFraniere:

Hi. Thanks for doing this. Can you hear me okay?

Michael Caputo:

Yes.

Sharon LaFraniere:

Okay. This is for [Senior administration official]. I wanted to follow-up on the question asked earlier about whether or not you are committed to discuss with the Advisory Committee any emergency use authorization requests for one or more of these vaccines and also how likely is it that you will seek and EUA

approval for one or more vaccines?

[Senior administration official]:

Yeah so first of all it's a really good question and we appreciate the dialogue on this. I think you will also very much so appreciate this is an extremely dynamic and unpredictable situation. And I don't mean to it's not a cliché that's just what it is. We don't know how well these vaccines are going to work until we finish our clinical trials process. At that point we do - we'll do an assessment and say what makes sense in terms of the regulatory pathway for the product.

And so again we use the term emergency use authorization. Well that's contingent on so many different parameters which we just don't have those answers right now. So if you say we're going to get an emergency use authorization for this vaccine, well the answer is it's going to depend and we'll make that decision once we reach that.

I think, you know, again emergency use authorization or should you get licensure and how to go through those processes we're going to have to make those decisions once we have more information. But having said that again the key message is that the regulatory processes will be followed. The FDA will independently review the applications, review all the data that's available at all those appropriate processes will be followed.

Coordinator:

Next question is from Peter Sullivan from The Hill. Your line is open.

Peter Sullivan:

Hi thanks. I wanted to ask about the needles and syringes and vials you touched on a little. There have been some questions about some of the

companies that have gotten contracts, you know, about how much capacity for example Retractable Technologies has and it apparently, they do some manufacturing in China. Is that a concern?

Marathon is apparently a distributor and doesn't actually do manufacturing itself is that right? And then on ApiJect I understand that's a new technology that's never been used before. So I mean do you have any, are you confident in I guess the track records of all these companies and that they will add up to enough needles and syringes and vials by the end of the year?

[Senior administration official]:

It's [Senior administration official] on the latter absolutely yes. And I think I'm just going to reiterate [Senior administration official] earlier message which is not only have we looked at this in detail we have built in contingencies and hopefully contingencies for everything we can think of as it relates to this. We - before this process began, we had some of this stuff long before Operation Warp Speed became a reality, we had the stuff on order.

I think if I look back the very first orders for some of this stuff were in the February, March time frame. And Operation Warp Speed didn't come about until May. So Dr. Kadlec and his group at ASPR had anticipated that we might need these and put things on order and we got in the queue pretty darn early for some of this.

We in many cases have expanded to your point we've made investments in expanding domestic production capacity for things where we may feel a little bit more vulnerable to foreign production. So we've made those investments. And, you know, as I mentioned in terms of the numbers, we have ordered probably a lot more than we're ever going to use so we've built in some slack as it relates to that.

So I think, you know, what I would say is we feel very good about it but we're not going to rest on any laurels. We have teams of folks, project teams that are going out and working with these manufacturers where we've made investments. They are checking, they are identifying barriers. In some cases we are importing raw materials using accelerated transportation methods from overseas.

If we hear one of our suppliers saying it's going to take me six weeks to get the metal, I need for these needles we send a plane the next day and have it there in 48 hours. So those are the types of interventions we are making to absolutely reduce the probability of any shortcoming. It's never 100% but I think the message for the American people is we are doing everything possible to minimize the possibility of some sort of breakdown in the process.

Michael Caputo:

Next question.

Coordinator:

Next question is from Jason Mast with Endpoint News. Your line is open.

Jason Mast:

Yes thank you very much. I was just curious on the Pfizer vaccine deal how exactly that price was reached and if we should expect that to be a benchmark for vaccine dose size going forward?

[Senior administration official]:

Does size did you say?

Jason Mast:

No sorry the price of the vaccine that Warp Speed buys going forward.

[Senior administration official]:

Yes so, the Pfizer contract is a very unique one along several dimensions. And let me just mention a few of them. They're all public. We have not made a prior investment in Pfizer. So we did not invest in research and development as we have for several other candidates as you know.

As [Senior administration official] said we did not invest in their clinical trial. They are investing in that themselves. And perhaps most important we have no obligation to buy even the 100 million doses if they do not achieve either emergency use authorization or licensure from the FDA. So this is the lowest risk contract that the government has engaged in thus far.

And I what I can tell you without getting into specifics the price point relative to the all-in cost of what we are engaging in with the others is very, very competitive. So we're pleased with the deal we have. By the way I should mention that the Pfizer contract includes them playing a big role in the logistics of distribution. They've already developed distribution containers and they will play a big role in the distribution directed by us but executed by them.

So we are very pleased with that. And just I think the main message is that is an all in price that includes absolutely no investment in R&D on our part, no investment on our part in the clinical trial, much less risk at the back end because we only buy it if it's approved by the FDA and they also have a distribution component that the others don't.

Coordinator:

Next question is from Laura Strickler with NBC News. Your line is now open.

Laura Strickler:

Hi. Thank you for this call. Have you made any decisions at this point about who will get the vaccines first like healthcare workers OR nursing homes?

And are you also working with anyone else in the federal government working on a public information campaign to urge people to take the vaccine? Thank you.

[Senior administration official]:

Okay so this is [Senior administration official] and I'll take the first one and hand over to [Senior administration official] for the second one. So again it is an incredibly insightful question. It's a question that we are deliberating literally again on an hourly basis. One of the things though that with the experts across our government we, but it's incredibly difficult to answer because we really don't know if these vaccines would be safe and effective in populations that may be most formidable to this infection.

So for example in populations that are 75 or 80 years old which we all know have very high complication rates that are certainly vulnerable to this infection we just don't know how well this vaccine will work. The way that we answer that question is we appropriately designed clinical trials which I feel very strongly that we have done so that we understand if the vaccine will work for those vulnerable populations. If it does, they become obviously one of the groups that can and should receive a vaccine.

If it doesn't then we're going to have to again reassess strategy and think this through. Protecting personnel that are at risk I think we would all agree that the healthcare workers taking care of COVID-19 patients day and night I mean those are American heroes. And so those populations may be very appropriate. But we need to understand that the vaccine would be safe for

them and that the vaccine would be effective for them.

I want to make a final point that [Senior administration official] started us on today was this idea of that we have vaccines but that we also have therapeutics. And the advantage of Operation Warp Speed having this very thoughtful and integrated portfolio is that some of these therapeutic products may be very useful while we're waiting to get a vaccine in to protect certain populations.

So for example if elderly patients in long-term care facilities are becoming ill having a therapeutic to not only treat that patient but also reduce their transmissibility so that they're not spreading that infection to other people that's a nice way to create a firebreak for it, you know, as the pandemic spreads and we can sort of stop it so that as we're waiting for vaccines to become more effective.

And that some of those therapeutic products like the antibody products the [Senior administration official] brought up they may be actually a really good choice for elderly populations especially if the vaccine is less effective in elderly populations.

[Senior administration official]:

And then I think on your other question about promoting the value of vaccinations and so forth a couple of things that are important. One is at this point time we are most focused on two things and that is getting subjects into the clinical trials and we're promoting a lot of that all over the country very successfully by the way. And as I think I mentioned a little bit earlier promoting the donation of convalescent plasma.

And I think I also alluded to the fact that the President's over the American

Red Cross as we speak helping us with that mission. We want 175,000 units of donations for convalescent plasma in the month of August and we want 500,000 units total by this fall. And a lot of our effort is around promoting right now those types of donations.

When you talk about promoting vaccines, we are walking a very fine line because as [Senior administration official] has mentioned a couple of times, we don't know in whom these vaccines are going to work and who they're not. We don't know as I mentioned earlier how many doses we're going to have at what time of the year.

This could be, you know, it's theoretically possible we could have 10 million doses in the middle of October or the end of October. It may not be till the end of December, it may be in early January. So the fine line we're walking is getting the American people very excited about the potential of vaccines and then missing on expectations versus, you know, having a bunch of vaccines in the warehouse and not as many folks want to get it.

So what are we doing, how are we addressing that? Working with Michael Caputo -- who is right here in the room -- and his whole ASPA team the strategy of our communications and our promotion of vaccines is going to be what I would call a much more truncated one time wise.

Think about it as a four to six-week period of time very intense, multi-channel, highly targeted based on what we learn about the vaccine. So you may not hear a lot about promoting vaccines over the airwaves in August and September but you'll be overwhelmed by it come November so that's one thing.

And the second thing is we are already engaging many community

associations who are going to help get this word out and help build trust for vaccines. So we're dealing with those who work with minority populations, those who work with Native American populations, we are working with the American Medical Association, the pediatrics, the American Association of Pediatrics and we are keeping them informed. We have regular interactions with them.

In fact we've kind of formed a committee that participates in this and their purpose is to bring us concerns or uncertainties from the population and we feed that into our - into the messaging that I have described will come later this fall. But also, we're pushing messages out and they are already engaging with their relative, you know, associations if you will, members of their associations.

Without giving you specifics I can tell you this is already working. When we look at those who have registered for the early clinical trial that began this week, we see a great deal of diversity in those who have registered. Now they're not in the door and fully enrolled yet but they have registered. And we're very, very pleased with minority population content of those registrants.

Michael Caputo:

This is Michael Caputo. We have time for one more question. I do want to remind you that the statements and comments by [Senior administration official] or [Senior administration official] are on background attributable to a senior administration official. One more question.

Coordinator:

The last question comes from Will Feuer from CNBC. Your line is now open.

Will Feuer:

Yeah, hi. Thanks for taking my question. I wanted to ask about the contract that was announced earlier this week by President Trump so Fujifilm the \$265 million contract. I was hoping to get a little more context around that what role is that going to play in the overall vaccine process and how important is that to the distribution or the eventual distribution of vaccines?

And also in terms of that investment who does that go to? Does that go - does all \$265 million go to Fujifilm or is that split with other contractors? And also for all of these contracts will they be made public at any point?

[Senior administration official]:

So it sounds like I'm trying to parse my way through a few questions there. Let me answer broadly. So the concept is vaccine manufacturing capacity. As you know that we have been very proactive to figure out where that vaccine manufacturing capacity is available and ensure that it is ready to go and ready to scale for the vaccine products that we need to make. The opportunity with Fujifilm is one of many examples where vaccine manufacturing capability is available and so therefore reserving that and having that ready for scale is part of our overall strategy.

We build that strategy to be redundant. We want to be able to, you know, have more capacity than we have vaccines to make. Usually it's the opposite problem because vaccine manufacturing capacity it tends to be limited. So I think we've done a really nice job as a government to seek where that capacity is available and to make individual fit for purpose contracts so that we can utilize them.

Michael Caputo:

Okay, thank you very much everyone. We'll be scheduling another one of these calls on Operation Warp Speed in the near future. There will be more

news coming from us on a regular basis. You know how to get a hold of us through Natalie Baldassarre who is the primary media contact for Operation Warp Speed. And I wish you all a very good day. Thank you for participating.

Coordinator:

This concludes today's call. Thank you for participating. You may disconnect at this time.

END