AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 117–085

VACCINES FOR VETS: OUR BEST SHOT AT ENDING THE COVID–19 PANDEMIC

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

FIRST SESSION

FEBRUARY 24, 2021

Printed for the use of the Committee on Veterans' Affairs

Available via the World Wide Web: http://www.govinfo.gov

U.S. GOVERNMENT PUBLISHING OFFICE

45–822 PDF WASHINGTON : 2021

SENATE COMMITTEE ON VETERANS' AFFAIRS

JON TESTER, Montana, *Chairman*

PATTY MURRAY, Washington
BERNARD SANDERS, (I) Vermont
SHERROD BROWN, Ohio
RICHARD BLUMENTHAL, Connecticut
MAZIE K. HIRONO, Hawaii
JOE MANCHIN III, West Virginia
KYRSTEN SINEMA, Arizona
MARGARET WOOD HASSAN, New Hampshire

JERRY MORAN, Kansas, *Ranking Member*
JOHN BOOZMAN, Arkansas
BILL CASSIDY, Louisiana
MIKE ROUNDS, South Dakota
THOM TILLIS, North Carolina
DAN SULLIVAN, Alaska
MARSHA BLACKBURN, Tennessee
KEVIN CRAMER, North Dakota
TOMMY TUBERVILLE, Alabama

TONY MCCLAIN, *Democratic Staff Director*
JON TOWERS, *Republican Staff Director*

C O N T E N T S

FEBRUARY 24, 2021

SENATORS

	Page
Tester, Hon. Jon, Chairman, U.S. Senator from Montana	1
Moran, Hon. Jerry, Ranking Member, U.S. Senator from Kansas	2
Manchin III, Hon. Joe, U.S. Senator from West Virginia	9
Tillis, Hon. Thom, U.S. Senator from North Carolina	11
Murray, Hon. Patty, U.S. Senator from Washington	13
Boozman, Hon. John, U.S. Senator from Arkansas	15
Hirono, Hon. Mazie K., U.S. Senator from Hawaii	17
Tuberville, Hon. Tommy., U.S. Senator from Alabama	19
Blumenthal, Hon. Richard, U.S. Senator from Connecticut	20
Sinema, Hon. Kyrsten, U.S. Senator from Arizona	22
Hassan, Hon. Margaret Wood, U.S. Senator from New Hampshire	24

WITNESSES

Richard A. Stone, MD, Acting Under Secretary for Health, Veterans Health Administration, Department of Veterans Affairs, Accompanied By: Jane Kim, MD, MPH, Chief Consultant for Preventive Medicine, Ralph T. Gigliotti, FACHE, Network Director, VISN 19: VA Rocky Mountain Network, William P. Patterson, MD, Network Director, VISN 15: VA Heartland Network	4

APPENDIX

Richard A. Stone, MD, Acting Under Secretary for Health, Veterans Health Administration, Department of Veterans Affairs, prepared statement	32

STATEMENTS FOR THE RECORD

Moderna, Inc.	36
Pfizer	44
Dr. Richard Nettles, M.D. Vice President of U.S. Medical Affairs, Janssen Infectious Diseases and Vaccines. Johnson and Johnson	48

QUESTIONS FOR THE RECORD

Response to Questions for the Record submitted by:	
Hon. Jerry Moran	54
Hon. Sherrod Brown	59
Hon. Kyrsten Sinema	61

VACCINES FOR VETS: OUR BEST SHOT AT ENDING THE COVID–19 PANDEMIC

WEDNESDAY, FEBRUARY 24, 2021

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 4:12 p.m., in room G50, Dirksen Senate Office Building, Hon. Jon Tester, Chairman of the Committee, presiding.

Present: Tester, Murray, Brown, Blumenthal, Hirono, Manchin, Sinema, Hassan, Moran, Boozman, Rounds, Tillis, Blackburn, and Tuberville.

OPENING STATEMENT OF CHAIRMAN TESTER

Chairman TESTER. I call the hearing to order. Dr. Stone, I want to thank you for being here with your team once again. We appreciate what you do, and thank you for being here.

Today, with two vaccines authorized for emergency use and being distributed across the country, we will take stock of how VA is doing in terms of reaching its work force and the millions of veterans that the VA serves. It is my focus to bolster the vaccine supply chain and ensure there is a system to distribute the vaccine quickly and efficiently to all veterans, regardless of where they may live, and I know this is a goal shared by Senator Moran also.

From what I understand, the Department is excelling in getting shots into arms in a safe and timely manner once doses are received from the Department of Health and Human Services. I want to commend you in your efforts to administer more than two million doses to veterans and employees so far, outpacing the private sector.

Yesterday, Senator Moran and I had a productive conversation with Dr. Kessler and General Perna, the Biden administration officials responsible for development, manufacture, and distribution of coronavirus vaccines. We told them that the VA has proven its ability to quickly deliver vaccines where they are most needed, and that the Department already has the capacity to deliver above and beyond its current allotment. Moving forward, we will continue to press them for a larger allotment for the VA, and we will expect you to do the same.

To date, the Department has only received about 2.3 million doses. That means we still need about 17 million more doses to get veterans and staff fully vaccinated.

Beyond concerns with the overall supply chain, which are being addressed, I remain mostly focused on how we can better reach vet-

erans in rural, remote, and underserved areas. The VA has piloted a vaccine fly in program for rural areas of Montana, like Havre and Kalispell, and to communities in Alaska, which I think is an innovative way to reach rural vets.

However, we know that barriers remain to getting our rural veterans vaccinated in Montana and across the country. That is why we wanted Ralph Gigliotti from VISN 19 and Dr. Patterson from VISN 15 with us here today, and thank you folks for coming to this hearing.

I look forward to hearing more about how you, Dr. Stone, are allocating vaccines to different VISNs, and then how you, Ralph and Dr. Patterson, are allocating them to the different medical facilities within your VISN. Whether a veteran lives next door to a VA medical center or hundreds of miles away from the nearest one, all veterans must have equitable access to getting this vaccine.

I know that reaching areas, particularly highly rural and frontier areas, brings both logistical challenges and potentially higher refusal rates than elsewhere, but we have to get this right. And we have to do a better job of communicating with veterans, setting their expectations, and giving them a better idea of when, how, and where to get a vaccine when it is their turn. Addressing these issues of both supply and demand are truly our best shot at ending this pandemic and getting our economy back on track.

I want to thank you all for being here today, and I look forward to the conversation ahead.

Senator Moran, you have the floor.

OPENING STATEMENT OF SENATOR MORAN

Senator MORAN. Chairman Tester, thank you very much, and thank you for the conversation we had with the general and the doctor yesterday. Good afternoon to everyone here today. I am pleased, Mr. Chairman, that we are conducting this hearing on this important topic. A shot in the arm is perhaps the most important thing we can do to improve our country's well-being, both economically and health-wise, and we certainly want to make certain that veterans are vaccinated as quickly and as time-efficiently as possible.

I give special welcome this afternoon to VISN director, Dr. William Patterson. Thank you for your leadership. Thank you for the relationship that we have and your good works with my staff. I am very grateful for that.

Throughout these past 11 months, our Nation has faced nearly an overwhelming challenge of responding to coronavirus. We have all been impacted by the loss of lives, strain on our health care system, upheaval in education structures, and economic disruptions. Through the hard work and determination of our country's scientific and medical communities, we now have two promising and available vaccines for COVID–19. With millions of Americans getting their doses each week, we are getting closer and closer to beating the virus.

In addition to our individual actions to help keep our neighbors and ourselves safe and healthy, those of us on this Committee have a special responsibility to America's veterans. Through cooperation with and oversight of the VA, it is our job to make certain that

American veterans are best served and best taken care of through these extraordinary times.

The VA's dedicated work force has answered the call, and we honor and thank those who report to work every day to care for our heroes on the front lines of this pandemic. Remember especially those that have died in the course of their work, many of them veterans themselves, serving their brothers and sisters in uniform.

I think we can all agree that the VA has stepped up during this pandemic, making themselves available to veterans far and wide, and executing numerous fourth-mission assignments. I want to highlight that earlier this month employees at the Kansas City VA, faced with cancellations at a mass vaccination event, conducted rapid outreach to eligible veterans to get shots in arms, and kept working until nearly midnight to make certain no doses went to waste. I commend and congratulate those who were responsible for that and those who made certain that the shots occurred.

As we move closer toward the home stretch—hopefully to a home stretch—with each passing week, I seen immunization numbers continue to rise and ICU admissions numbers fall. It is critical that we not lose sight of our core mission: taking care of our veterans.

I want to make certain that the VA is doing its best work in taking care of veterans and seeing that this vaccination rollout is working in the most efficient and expeditious manner possible. My staff has been having weekly calls with the Department, but despite that we continue to learn things through news articles and veterans that we did not otherwise know. This leads to a time-consuming process of requesting a call, facing scheduling delays to connect with proper people at the VA, and finding out weeks later things we should have known, could have known, much earlier had we been informed directly.

One example of this is the use of algorithms to determine the vaccine eligibility prioritization. We are hearing now that veterans who should be at high risk, based on disability or injuries, are not being prioritized properly in the program, and I look forward to hearing from Dr. Stone and others in regard to this topic.

At the same time, we are learning that the VA is continuing, perhaps even expanding, vaccination efforts for elements of the Federal work force from other departments and for caregivers. A concern is that the VA could be overextending itself without enough oversight to ensure smooth processes or make certain its primary patient population is getting vaccinated. I look forward to the assurance that that is not a problem.

The VA's unique mission needs to be managed in accordance with the population it serves, and existing system and infrastructure in place to execute it. Congress, in recent years, has legislated significant reforms to put veterans at the center of their care decisions, and we must make certain that even in times of great strain veterans do not fall through any gaps.

Particularly, I want to make certain that veterans in rural and highly rural areas, similar to what Senator Tester, Chairman Tester, said, that those veterans in that part of the country are not overlooked. My staff and I have received multiple assurances from VHA officials that rural vaccination efforts would have access to a

fair share of allotment and at a pace equal to their urban counterparts.

I visited the Colmery O'Neil Hospital in Topeka on Monday, on my return to Washington, DC, and I was pleased to see the efforts that are underway to make sure that rural veterans are not left behind, that CBOCs are being utilized, and I raised the topic, although I do not think the answer was the one I would hope to hear, that even our Community Care providers are capable of providing vaccinations to veterans through the VA.

I am concerned that the Department lacks a standard communication strategy for outreach to veterans, and that the decisions are largely VISN dependent. VISNs are also delegated authority to draft their own vaccination plans, which could lead to inequities across VHA, and while I am generally for local control and decisions being made locally, I want to make sure that veterans across the country receive what they are entitled to and what they are eligible for.

I have some concerns about the VA's plan to direct veterans to pharmacies in the community for vaccines and from what allotments those doses would be coming. So while I think it could very well be a good idea, I want to know what it is detracting from and utilization of those local pharmacies could be very helpful in vaccinating rural veterans.

I want to make sure it is the best course of action to optimize vaccine rollout in the ways that reach veterans quickly, efficiently, and in a way that bolsters public health rather than placing unintended strains on vaccine supplies in communities or risking surplus at a VA site. This process is something we ought to get right, and the details matter.

Mr. Chairman, I look forward to a robust conversation today as we look to find ways to improve upon the process in place and make certain that those who serve in uniform are best served by the department created to care for them. And with that, Mr. Chairman, I yield back.

Chairman TESTER. Ranking Member Moran, thank you for your Statement. Dr. Stone, I understand you are going to be the point person here to testify and the others will be here for questions. You have 5 minutes. Please know that your entire written testimony will be a part of the record. You may proceed.

STATEMENT OF RICHARD A. STONE ACCOMPANIED BY JANE KIM, RALPH T. GIGLIOTTI AND WILLIAM P. PATTERSON

Dr. STONE. Thank you, Chairman Tester, Ranking Member Moran, and distinguished members of the Committee. Thank you for the opportunity to testify today about the Department's response to the COVID–19 vaccine rollout. You have already recognized a number of the team members to my left, but Dr. Jane Kim is our Chief Consultant for Preventative Medicine, and I am accompanied also by Dr. William Patterson, Director of VISN 15, and Mr. Ralph Gigliotti, Director of VISN 19.

I would like to acknowledge the somber milestone achieved this week of 500,000 deaths of our fellow Americans due to COVID–19. Of that number, just over 10,000 are veterans, and 131 are VA em-

ployees. We collectively mourn all of those lost and continue our pledge to save every possible life that comes into the VA for care.

Throughout this pandemic, VHA employees have stood on the front lines, courageously delivering care to America's veterans, and for the American population broadly. That heroic effort has now turned to distributing and administering as many vaccine doses as possible. It has been an emotional time for many in health care, as teams who fought this disease on the front lines have begun to have hope that relief is coming.

We are absolutely committed to get as many veterans vaccinated as quickly as we can. The logistics and the delivery of these vaccines is very complex and requires new and unique processes. We are reaching out to veterans when they are eligible, and we encourage veterans to use our Web-based "Keep Me Informed" tool to get updates about VA vaccinations.

Yesterday, as of February 23d, VA had administered well over 2.1 million doses of the vaccines. These include over 1.1 million first doses to veterans and 484,000 doses, first and second doses, to VA employees, which have inoculated well over 90 percent of our clinical staff. VA is currently providing vaccine at more than 215 sites nationally, and we are using virtually all the doses that we receive as soon as they arrive each week. And we have the capacity to deliver between 300,000 and 600,000 doses weekly.

More than 6 million veterans depend on us for their health care, and CDC plans to provide us with first and second doses for each of those 6 million, as well as our 400,000 employees. And we are focusing our efforts on enrolled, eligible veterans who are listed in the highest-risk categories. Veterans who are not yet receiving care through the VA health care system are encouraged to enroll now.

We remain committed to health care equity across multiple dimensions, and that also applies to our vaccination efforts. We are working hard to reach our most rural veterans and those communities hit hardest by the pandemic. For rural veterans, we have developed distribution guidance to facilitate safe transportation of vaccines to rural areas. Our planning has ensured equitable access and distribution of vaccines to racial and ethnic minorities disproportionately affected by the COVID–19 pandemic. We are very pleased that we are seeing relatively comparable outcomes across race once veterans are enrolled in our care.

In preparation for the vaccine rollout, our teams wanted to ensure that wherever possible every veteran felt confident about receiving their shot. We recognize that the most trusted voice in making health care decisions is a patient's health care provider. Therefore, our outreach plan features VA staff and providers proactively calling the veteran. They serve to provide information, answering questions, and scheduling appointments for vaccination. This has helped to overcome barriers such as vaccine hesitancy. In fact, enrolled veterans over age 75, the group currently prioritized for vaccination, 25 percent of white, 28 percent of Hispanic, and 30 percent of black veterans have been vaccinated.

I am incredibly proud of our teams who are doing outreach, responding to questions and dedicating themselves to this effort. While we have not seen racial or ethnic disparities in vaccinations so far, we will continue to actively manage equity in our system.

I would like to specifically address our support to those caregivers of veterans participating in the Program of Comprehensive Assistance for Family Caregivers. VA offers testing and vaccinations to eligible family caregivers, and so far more than 2,000 caregivers and 12,700 veterans involved in this program have received at least their first dose of vaccine.

Before I close, I would like to thank this Committee for your support in passing the CARES Act, and I am pleased to report that we are on track to fully execute the remaining CARES Act funding in the coming months. Those funds have facilitated the agility VHA has demonstrated over this pandemic.

The Biden administration's American Rescue Plan will sustain our response and ensure that we can respond to the inevitable wave of delayed and deferred care. Your support remains essential to our continuing effort to provide excellent care for veterans and their families, and I am grateful to this Committee and its leadership for your partnership.

My team and I look forward to answering your questions.

Chairman TESTER. Thank you, Dr. Stone. I appreciate the testimony. We will start with the questions now.

I understand, and correct me if I am wrong, Dr. Stone, the VA is receiving about 125,000 doses per week, and the VA is getting those administered within a week, for the most part, all of them. Dr. Stone, you said that the VA has capacity to administer 300,000 to 600,000 per week, and I know this is contingent upon national supply. But what is your ideal weekly allocation of doses?

Dr. STONE. Between 300,000 and 600,000 a week. I am quite pleased, sir, that we just received a call before we came over here that we will, next week, receive almost 600,000 doses.

Chairman TESTER. That is good news, Moran. Look what happens. That is good. That is really good.

So then the question is, now you have got some vaccines to work with, at least in the short term, and hopefully that will continue in the long term. How do you decide how those vaccines are distributed to the VISNs?

Dr. STONE. I am going to defer to Dr. Kim for the answer to that.

Chairman TESTER. Okay.

Dr. KIM. Hi. I will be happy to speak to that. So my name is Jane Kim. I am a general internist and preventive medicine physician, and since September 2020, I have been leading the COVID national vaccine planning team for VA.

So in terms of vaccine allocation, our strategy really flows out of the Health and Human Services strategy, which uses a pro rata approach to determine vaccine allocations for the country. So for each State jurisdiction or Federal entity, the allocation of vaccines is determined by population, using a pro rata approach.

We, in VA, follow a similar methodology using pro rata, but primarily base it on the CDC priority phase that we are currently in. So we are currently in Phase 1b, which is mainly 75 and older veterans. So for each VISN we take the number of veterans in that VISN who are 75 and older, and the denominator is the number of veterans in our system who are veterans 75 and older. And that is all of our veteran users of our health care system.

Chairman TESTER. Can you have those—you have got those metrics lined out so you are comfortable that you have the metrics for veterans in each VISN that are 75 years and older?

Dr. KIM. Yes.

Chairman TESTER. Okay.

Dr. KIM. Before we started this we did a population enumeration and got those numbers nailed down.

Chairman TESTER. Okay. So that is fine. Thank you. And then, Ralph Gigliotti, at the VISN level, how do you decide vaccines that go to each VA medical center within your VISN, or each State? Is it done the same way?

Mr. GIGLIOTTI. Sorry. Yes, Mr. Chairman. It is done the same way. We base it on the 75-plus age with patients, patients that may be on hemodialysis, organ transplant, chemotherapy, that type of thing.

Chairman TESTER. Okay. So I know you have got your boss sitting here, just to your right a couple of paces down, or maybe right next to you, as far as that goes. The question is, do you feel like VISN 19 is getting the adequate number of doses?

Mr. GIGLIOTTI. We are using the formula that is being used. We look forward to when the volume increases and we have detailed plans at all eight of our health care systems to roll out more vaccine.

Chairman TESTER. How much lead time are you able to give the veterans to know when they can be vaccinated?

Mr. GIGLIOTTI. So we do scheduling in advance. We trust the weekly supply that we have been getting. We get excellent communication from Dr. Kim, from Dr. Stone, so we know in the upcoming weeks what we are projected for, and we go ahead and schedule out for that.

Chairman TESTER. So the 600,000 doses aside, that you got today, because that is good news, are you able to give the veteran 2 weeks' notice? One week notice? Two days' notice?

Mr. GIGLIOTTI. So yes to all of that. We are able to schedule in advance, 2 weeks to 4 weeks is the norm. However, there are some situations where we are able to call veterans in on a day or two's notice, because when we reach out to the veteran we ask what type of lead time do you need to come in for a vaccine. And so if we have an extra supply for a particular week we are able to bring somebody in on a day or two notice also.

Chairman TESTER. Thank you. I have got some more questions but there will probably be another round. Senator Moran.

Senator MORAN. Mr. Chairman, thank you, and thanks again to Dr. Stone and his colleagues for joining us today. I am perhaps exploring some of the things that Senator Tester just did, but I want to see if I can be specific or get a specific answer.

Dr. Stone, in your written testimony you provided the insight that the VA's allocation process to VISNs is similar to how HHS allocates the vaccines to the States, and that is, again, this population issue that Senator Tester just raised. Are the VISNs bound to this pro rata allocation formula when reallocating to the network of facilities they have within the VISN? So does the veteran population coming to the VISN, is that then translated into, in my case,

Wichita and Topeka as the same number, based upon veteran population?

Dr. STONE. We have given discretion to the regional leaders to distribute to their health care centers, based on refrigeration capacity and labor capacity, to deliver vaccine. And, therefore, that discretion has included the kind of thing you described in your opening Statement, sir, that sometimes we find that we have got some extra doses and we may reach below a risk population to even a younger veteran.

We know that the major risk of death and serious illness is based on age, and of all the variables, age seems to be the thing that stands out. And, therefore, we have followed the CDC guidance, but there is the flexibility, at the local medical center level, to reach to a lower group of risk should have vaccine available, because the transport of these vaccines is very difficult, especially the Pfizer vaccine.

Now, in your State, the nearly 20,000 doses that have come into your State, have been mainly in Moderna, and I am sure Dr. Patterson can correct me if I am wrong on that.

Senator MORAN. Dr. Patterson, let me ask this question to see, again, if I can get this answer. So does Wichita and Topeka get allocated based upon changes in conditions of VISN decision, or is it specific to we have this many doses, based upon population, and based upon the number of veterans that utilize Wichita and the number of veterans that utilize Topeka, Topeka Leavenworth, that is how we allocate them?

Dr. PATTERSON. It is a little bit in that way, Senator. Of course, we prioritize according to the guidelines we get from VA Central Office in terms of scheduling veterans to come in. But we do not have enough vaccine each week to do that entire broad population at one time. So what we have done is we allocated a minimum amount to each medical center.

So for instance, Topeka and Eastern Kansas, Kansas City, Marion, Poplar Bluff, will all get a minimum of 600 doses each week. That is the minimum. Now, if they have the ability to do more, or if they have scheduled an event, if we have an amount above that, which we generally do, then we supplement that. So they are prioritizing based upon the age group, over 75, and then if they get all those done, well, first the CLC patients, then the over 75. If they need to go between 65 and 75, they do that.

But as you referenced in your earlier comments about the event in Kansas City, we had 200 people not show up one night for vaccines. So we have standby lists ready to go, and we start calling those veterans. And I was out there that night, at 8 that night, and stayed until about 10, and it was amazing to watch the parking lot of people just pulling in, flipping off their lights, and running into the building, even carrying their kids in pajamas sometimes, to be sure that they could get a vaccine.

Senator MORAN. Again, thank you for that response, that response to supply.

The conversation that we just had, Dr. Stone and Dr. Patterson, lends itself to my next question. My staff has been informed that the VA's risk stratification framework includes vaccinating veterans based upon occupation, starting in Phase 1b with frontline

and essential workers. So another way to allocate will be based upon what a veteran's occupation is—are they an essential worker. Can you clarify whether it is VACO's guidance for VISNs and facilities to vaccinate based upon occupation?

Dr. STONE. I can. Certainly in 1b, frontline essential workers are identified by the CDC, so that is where that came from. As we have identified it, I think Ralph Gigliotti probably has the best story when it comes to that, of how they approached frontline essential workers. Mr. Gigliotti, do you want to go ahead?

Mr. GIGLIOTTI. Sure. What we did was identify the various caregivers across all eight of our health care systems, and then using the employee stratification, offer it to employees in order to ensure those that came in contact with veterans were eligible, able to receive the vaccine. And it has gone really well, and we have right now 76 percent of our employees have received a first dose, and many of them have also received a second dose.

Senator MORAN. I think I am talking about the veteran's occupation, not the staff member's occupation, right?

Dr. STONE. Right. What I was referring to, and I apologize for catching Mr. Gigliotti on this one, was that they had identified and called veterans who were part of the local police department and had reached out to them and said, "Look, all the police officers in this community who are veterans, we have got vaccine for you, as part of the 1b allocation," thus unloading the community to it provides. And please clarify.

Mr. GIGLIOTTI. Yes. That was with the Havre fight that we did in Montana, and that was with first responders from the Rocky Boy Native American Nation.

Senator MORAN. My time has expired, but I would ask this followup question. You can answer it later. Is there a way to verify a veteran's occupation to make sure that they are in the occupation that they say they are?

Chairman TESTER. Good enough. Thank you, Senator.

Senator MORAN. Apparently, you do not have time to answer.

Chairman TESTER. I am interested to know that too, actually.

We will go to Senator Brown, virtually, if he is there. Going once. Going twice.

Okay. Manchin is up.

SENATOR JOE MANCHIN

Senator MANCHIN. Okay. Thank you so much, Mr. Chairman, for being so kind.

Dr. Stone, I am pleased that we have so many, 20, vaccine candidates reaching the final stages. I come from the State, the beautiful, beautiful State of West Virginia. Very, very patriotic and an awful lot of veterans. And I imagine when the vaccines are approved, some of them will need specific storage temperatures again. And I would hope you all would take into consideration, in some of the smaller rural areas, we do not have the ability to handle that. So when you are designing what vaccines are going to go to what area, will you make sure that basically it is matched up with the capabilities of handling the vaccine so it does not spoil, it is not wasted? Is that part of your——

Dr. STONE. It is, Senator, and as you know, because of the rural nature of much of your State, we have shipped over 37,000 doses to your State. It has all been Moderna, which has been easier to handle at a –20 degrees. None of it has been Pfizer. It is just too difficult to move that around.

Senator MANCHIN. Absolutely.

Dr. STONE. And it has given us the ability to actually immunize about 38 percent of the over–75-year-old veterans in your State.

Senator MANCHIN. We are going to need a lot more, as you know. All the States do. We understand that. But in the rural States such as ours, as long as you make sure that you are identifying the type of facility it is going to take in order to handle that new vaccine when they come, whether it being J&J or other ones, I understand, are coming on quite rapidly.

Dr. STONE. They are, and I will defer to Dr. Kim. It is not clear to us what the guidance is going to be from the FDA and the CDC on the utilization of the new vaccine that will come. That is the single-dose vaccine. And so I will defer to Dr. Kim.

Dr. KIM. Yes, Senator, I am sure you know from previous people who have testified here that the FDA is meeting this Friday to discuss the Johnson & Johnson vaccine and possibly authorize it if data looks favorable this weekend. And we, you know, in the scientific community, really like that vaccine because it is one dose, refrigerated, and can last apparently up to 6 months in a refrigerator, which makes it a great option for places that only have a refrigerator, such as maybe some rural facilities, maybe in your State. So it is a nice versatile option from a storage standpoint, as well as it is only one dose, which some veterans may really like.

Senator MANCHIN. Let me ask you this. In the weather conditions we have been having and some of the extreme weather around the country, have we lost, or has any of it spoiled, not being able to get to market or get to the end user?

Dr. STONE. We have had minimum wastage, and, look, every dose is a tragedy. We had, up in VISN 1 in the Northeast, a contractor who was cleaning up after a broken pipe with a flooded area, inadvertently unplug one of our negative–70-degree freezers and we lost a palette of the Pfizer vaccine, so we lost about 1,000 doses. And so that has been the largest loss that we have had.

Frankly, the VISN leadership have done the same sort of thing that Dr. Patterson did, at 8 and 9 at night where we are calling veterans and we have got cancellation lists. That is true across the Nation.

Senator MANCHIN. A lot of the people live in rural area. They do not have internet service. A lot of them are not on internet service. I know when you are contacting, trying to set your appointments up, what other, other than just a phone itself, how are you all able to communicate?

Dr. STONE. I am going to defer to Dr. Patterson and Mr. Gigliotti about how they are doing their scheduling.

Dr. PATTERSON. We do schedule as much as possible, but we also have some walk-in availability in a lot of places. But one of our big partners has been the veteran service organizations, so the Legion, the VFW. They have a lot of good connections in the community, and particularly in small communities where they are very strong.

We set up events there and they help us get the word out. We may use social media and robocalls and the local clinics, but that community connection really goes a long way.

Senator MANCHIN. I also was pleased to see the VA had been allowed to participate in the Defense Production Act committee and help determine the most effective ways to meet our Nation's needs. However, even with the great new developments we are seeing with vaccines, we need to be prepared to continue to deal with the COVID–19 on the long term, as we are seeing it, and if you are all prepared for that. So how has the VA's participation in the committee's decision on deploying the DPA helped you respond to the COVID–19 pandemic?

Dr. STONE. Sir, I think it is too early to say what our participation with the DPA has been. At this point, we are still working and we have briefed our new Secretary on our desire to be at the table in the Defense Production Act. But how the Defense Production Act is utilized as well as our role and our voice as the largest provider of health care services in the Nation is one that I think still remains to be seen.

Senator MANCHIN. Are you able to get all the equipment you need? Are you getting PPEs for your employees and everything?

Dr. STONE. Yes, sir.

Senator MANCHIN. And do you have your portable—in West Virginia we have a lot of the portable trailers that go around, trying to help people who live pretty far away from a facility or a clinic.

Dr. STONE. Yes, sir. In comparison to where we were 6 months ago, our supplies of PPE as well as our emergency stocks and our rolling stock is in much better shape than it was early in the pandemic, even a year ago.

Senator MANCHIN. Are you able to spin shots out of your portable, out of your portables?

Dr. STONE. We can, and we are.

Senator MANCHIN. Yes.

Dr. STONE. And we are using it mainly for transportation. We are finding, for efficiency sake, large open areas is a better place to go, and whether that is a parking lot——

Senator MANCHIN. They will come. They will come, sir.

Dr. STONE [continuing]. they will come. And so we are using that, but we are using the portable materials to transport and to assure the safety of the vaccine and the mixing of the vaccine when that is appropriate.

Senator MANCHIN. Thank you very much.

Chairman TESTER. Senator?

Senator MANCHIN. Mr. Chairman, I am indebted to you, being so kind.

Chairman TESTER. You can stick around for the second round too. Senator Tillis.

SENATOR THOM TILLIS

Senator TILLIS. Thank you, Mr. Chairman, and thanks to Senator Boozman for letting me go. I want to welcome you all here for the great work that you do. Dr. Kim, I want to—I feel like I have VISN 6 represented, to the extent that you are still doing work

down at the Durham VA, so thank you for that work down there, one of several great facilities we have in North Carolina.

Dr. Stone, I think in testimony before the House Appropriations Committee you talked about a mass vaccination down at the Salisbury facility as being successful. I would guess a lot of that depends on supplies as to whether or not you can replicate that. But do you see those mass vaccination programs as supply increases, maybe after we get another vaccine in the mix? Do you see that as being a key part of trying to step up the tempo on vaccinating veterans?

Dr. STONE. I do. I think the mass vaccination events-—in fact, on President's Day weekend, that 3 days, every single day we dispensed over 70,000 doses into veterans' arms. I think that Dr. Kim can go over what has actually been done at Durham and mass vaccination events, but we see that as the future, as we increase our supply of vaccines.

Senator TILLIS. Dr. Kim, I would like you to add to that, but I would also—I have been watching the final analysis of the Johnson & Johnson vaccine. We know logistically that makes everybody's life easier. We also know that it changes the way you may distribute them. So can you tell me a little bit on the mass vaccination strategy, but tell me to what extent are you already planning for the eventual availability of the one-shot, non-cold-storage vaccine that should enter the rotation? I know its efficacy is probably, for, I think, the more difficult cases about 10 percent lower, but certainly a highly effective vaccine.

So tell me a little bit about how that plays in it and also maybe start with the mass vaccination strategy.

Dr. KIM. Sure. I just will say that the mass vaccinations certainly are a really effective strategy to get shots in arms. You get a lot of vaccinators together and run a clinic all day, and you can do thousands. So I did one at Durham a few weeks ago and it was incredible. We had some frontline essential workers come through, a lot of older veterans. So I know those types of strategies are being used all across the country, including in North Carolina, and we will continue to do that. We are scaled up now to do that every weekend.

I will say, for the Johnson & Johnson product, I am very curious to see how that product will be discussed at FDA's Advisory Committee on Friday. You are right about the efficacy looking to be lower than the two products currently available, Pfizer and Moderna. You know, but I think we do see, in the data, at least the paper that came out today, that we will brief the committee, the advisory committee, that the Johnson & Johnson product does appear to protect against severe illness and death from COVID–19, which certainly is really the goal. We might want to get moderately ill or just mildly ill, but we certainly do not want to be in the hospital or to die from COVID. So we will see how that kind of plays out in terms of the discussion on the data.

In terms of how we would use this vaccine, we have talked about that a lot. You know, it is a great product because it is refrigerated, one dose, so it certainly could lend itself very well to mass vaccination. You would only need to go once, versus going back another

time. But, you know, I think we will see how the efficacy plays into that discussion as well.

Senator TILLIS. I will ask my final two questions and try to keep within time. The first question, you were talking about you have instances where you may have surplus supply, and you may have veterans—you have spoken about the distribution to police officers. But is there some sort of an appeal process or waiting list for people with chronic underlying conditions that are below the age cut right now and an outreach to them to potentially get them ahead?

Dr. KIM. Yes, Senator. In CDC's Phase 1c, which includes adults who are 65 to 74 years old, alongside of them are the younger adults who are 64 and younger who have a high-risk medical condition. And, you know, as we look at the phases of vaccination in VA, there are facilities, including Durham, who are at Phase 1c, and who are reaching out to some veterans in that age group who have a high-risk medical condition. So we are right there in terms of getting to that age group and that high-risk group.

Senator TILLIS. Okay. The final question has to do with moving forward with respect to the COVID relief package we are talking about, or funding that you already have in reserve. As your priorities either covered by the last phase of the COVID relief package or do you feel like that the funding priorities that are in the proposed COVID relief package are matched up with what you think your needs are?

Dr. STONE. I think that the CARES Act covered us well for what we saw as the needs to confront this battle against the virus. What we did not get covered, what we did not even consider, was exactly what happened after the great influenza of 100 years ago. There is a tremendous amount of health care that comes in a population that has not come in for its health care for the last year. And as much as we have encouraged urgent care, there is a huge tail of deferred and delayed care that we are beginning to recognize and talk to your staffs about, as we look at what the needs of this system are for the future.

In addition, the economic instability, where a veteran loses their health insurance, and then comes to us as the safety net, is resulting in our actuaries projecting very significant surge of care as we go into the remainder of this year and into the next few years.

Senator TILLIS. Thank you. Thank you all, and to the VISN directors, thank you. I am sure you are probably only behind VISN 6 in your performance. Thank you very much. You do a great job.

Chairman TESTER. Thank you, Senator Tillis. Senator Murray.

SENATOR PATTY MURRAY

Senator MURRAY. Thank you very much, Mr. Chairman. Dr. Stone, Dr. Kim, welcome, and I appreciate you being here with us today.

I want to start on the topic of how we promote vaccine confidence and fight disinformation and misinformation that can lead to vaccine hesitancy. We are seeing misinformation about vaccines spread really easily and widely across the internet, including through social media and messaging apps, coming from all kinds of sources and targeted to all kinds of people. And a lot of discussion around misinformation has been around communities of color.

But we know that disinformation is a serious concern among all demographics. That can lead to our veterans, caregivers, family members refusing a vaccine, even when they are offered one.

So I wanted to ask you, how is the VA and its Federal partners tackling this disinformation targeting all groups of veterans?

Dr. STONE. Senator, thank you. In my opening Statement I discussed the fact that we are very proud of the fact that we are not seeing, in communities of color, a vaccine hesitancy resulting in disparities. What we are seeing, however, in rural America, is much more hesitancy to take this, and therefore we have had a very active campaign to communicate, especially with our primary care providers, recognizing the fact that the most trusted person is your doctor or your care team, in really dispelling the problems of vaccine hesitancy.

I am going to defer to Dr. Kim, who has been close to this effort.

Dr. KIM. Sure. Thank you. Senator, we have thought a lot about this issue, ever since the fall when we knew these COVID vaccines would become available, and thought about how to get information out to our veterans that was science-based. We did focus groups with our veterans, especially those of color, to find out what they needed to know to help them make a decision if they were hesitant. And they told us they wanted the science. They wanted to know if a vaccine was safe and if it was effective. And they, as Dr. Stone said, wanted to talk to someone they trusted on their health care team.

So we combined all of that and have been working with CDC, who has a Vaccinate With Confidence campaign, to get science-based information on the vaccines in the hands of our clinicians so they could have conversations with their veteran. You know, there really is no substitute for the hard work of calling somebody and having a conversation with them, and it is 100 percent worth it when you can talk to one person and they figure out that they do want to get vaccinated. They tell their family. They tell other veterans. They tell their coworkers.

And so there is no substitute for that hard work, and we prepared our staff in VA for those conversations, and I have heard many stories from around VA about how clinicians are getting on the phone, talking with their veteran, helping them make those decisions.

Senator MURRAY. Well, thank you for that. And as we know, COVID–19 has had a disparate impact on communities of color. We know there has been a history of racism and medical mistreatment of people of color in this country, and those inequities have made the COVID crisis even more damaging for communities of color, and made it critical we do not let systemic racism block people of color from getting vaccinated.

I was really glad to hear that the VA has been working with communities of color to answer questions about—any questions they have about vaccines, but even when those questions are answered there are still barriers to access, and often these facilities are not located in the same community, which may force veterans to take time off from work, or find child care, or find transportation to reach a VA facility where the vaccine is offered.

So what is the VA doing to build trust within these communities and address those barriers to access?

Dr. STONE. Senator, I am going to defer to our regional leaders, Dr. Patterson, because you have done a very aggressive outreach to these populations. And, Dr. Patterson, if you could also discuss just about the relative access of your veteran population, and then, Mr. Gigliotti, if you could follow that.

Dr. PATTERSON. Right. Thank you for the question, Senator. If you look at VISN 15, and we cover the States of Kansas, Missouri, southern Illinois, some of southern Indiana, a little bit of northeast Arkansas and northwest Kentucky, within that area overall 95 percent of our veterans live within 60 minutes of a VA facility, whether it be a clinic or a hospital.

Now that tells you one story for an entire six-State area. However, if you look at individual areas within there, most of our medical centers follow that same pattern. Some of them, for instance Wichita, only has 73 percent who live within the CBOCs in the rural areas that are within 60 minutes, and some are all rural and have a lot more contact.

However, when you also talk about the way that our hospitals reach out to every ethnic group in order to get vaccinated, when we look at the large cities—St. Louis, Kansas City, even Wichita—our medical centers are located in the black communities. And so while Kansas City talks about a vaccine desert because there are no hospitals within a mile to five miles of the black communities, ours is in the middle of it.

And so we are not seeing the equity problem with vaccination because physically we are close enough to the community for people to get there and get vaccinated.

With our clinics, particularly in our metropolitan areas——

Senator MURRAY. Okay. I am over time. So, Mr. Chairman, in respect to you, I have a few other questions that I would like to submit, and I want to make sure we continue to watch this very carefully.

Chairman TESTER. Absolutely. Thank you, Senator Murray. Senator Boozman.

SENATOR JOHN BOOZMAN

Senator BOOZMAN. Thank you, Mr. Chairman, for having the hearing, very much. First of all, I want to thank you all for being here, and I want to give a big shout-out to the folks at the VA in Arkansas that are doing such a tremendous job, and truly our frontline workers and heroes and we are certainly impressed with the dedication that they are using to serve their communities and their State.

So, Dr. Patterson, thank you. A lot of people from northeast Arkansas use your services. I have been over to check it out and again, I really enjoyed the fact that you all are doing a great job.

Dr. Stone, I have had the pleasure of working with you now very, very closely for the last few years and I appreciate all that you do. I would like to talk to you a little bit about funding. The CARES Act provided $19 billion. The most recent data shows that roughly $9 billion of that has been obligated. Congress recently provided VA with its full request for medical care in Fiscal Year 2021. In

December, when Fiscal Year 2021 appropriate bills, and most recent COVID–19 relief package passed, VA indicated it did not need any additional funds to assist with response to the pandemic.

The current budget reconciliation package being considered in the House allocates $17 billion for VA to respond to the pandemic. I guess the question is, what has changed between December and today that leads the VA to require an additional $17 billion?

Dr. STONE. Senator, first of all, thank you for your kind comments and I appreciate and I have enjoyed——

Senator BOOZMAN. We do appreciate you very much.

Dr. STONE. Well, thank you, sir. I think there are two ways to think of this. First is the fight against the virus itself, and it was the foresight of this Committee, and frankly, all the oversight committees that got us the funding that allowed us to express the agility that we have had throughout this.

But there is another piece of this, and the other piece, as we turn to the final mile of this pandemic, that we are beginning to recognize this tremendous toll on the American population and the American veteran. It is mainly deferred and delayed care that begins to generate what we have asked the Biden administration to consider, and that is that we have a very substantial need that will peak in late 2021 and 2022, as we go through. Now, you could say, well, make this part of the budget, but this is not a sustaining problem. This is a bow wave that is going to come and go. And, therefore, when I was in DoD doing wartime funding, we viewed this as what we called contingency operation funding, which I view the American Rescue Plan and the CARES Act as a contingency operation. Then, as part of the budget, you have got your base funding that is going to be ongoing. And I know since we have talked budget a fair amount over these last few years this is something you and I have discussed before.

Senator BOOZMAN. Right. So we are prefunding probably additional funds needed in 2021. Would that be fair? And 2022?

Dr. STONE. I think a number of these funds will be needed in 2021, and especially——

Senator BOOZMAN. It is fair to say you have not—I guess I should ask, have we spent the dollars that we have allocated so far? Are we in good shape?

Dr. STONE. We are still in good shape. We have obligated a little over $7.2 billion. But we will obligate the remaining $10 billion before the end of this fiscal year.

Senator BOOZMAN. Okay. I am sorry. I did not mean to interrupt. So 2021 and 2022, your concern is we are going to need additional funding, that is kind of a one-time thing.

Dr. STONE. Yes, sir.

Senator BOOZMAN. Okay. Very good. One thing that has come up, I have heard from veterans in Arkansas who are eligible to get the vaccine and then their spouses were not, and maybe that veteran was pretty fragile and things, and then you still have the concern of the spouse coming in and out. Has there been any way of looking at eligibility for married couples?

Dr. STONE. Not successfully. I will tell you——

Senator BOOZMAN. Is that just the dollars-and-cents factor, or——

Dr. STONE. No. It has to do with the law that was written in the late 1990's.

Senator BOOZMAN. Okay. So you would need additional legislation.

Dr. STONE. We need additional legislative relief in order to get there. Yes, sir.

Senator BOOZMAN. Well, maybe that is something that the Chairman and I can work on.

Chairman TESTER. I agree.

Senator BOOZMAN. Thank you very much.

Senator MORAN. What about the Ranking Member?

Senator BOOZMAN. And the Ranking Member also.

Chairman TESTER. Absolutely.

Senator BOOZMAN. We do not want to leave him out.

Chairman TESTER. Thank you, Senator Boozman. Senator Hirono?

SENATOR MAZIE HIRONO

Senator HIRONO. Thank you, Mr. Chairman. I am told that, Dr. Stone, you have not been asked this question yet. What is your targeted number of veterans to be vaccinated?

Dr. STONE. We would like every veteran in America to be vaccinated, but right now, with the austere supply we have, we are targeting the 6 million active users of the system, Senator, and those 6 million active users are those that have depended upon us, and it is absolute that we must take care of those 6 million first before we look at any expanded population.

Senator HIRONO. When do you think you will be able to vaccinate those 6 million active users of the system?

Dr. STONE. It entirely depends on the available vaccine. Our goal was within a 120-day period to be able to vaccinate. It remains to be seen whether we will have a sustained supply. It is not terribly difficult to figure out that if you getting 125,000 doses a week, how many weeks it is going to take you to get to 6 million. If we receive a half a million this coming week and that is a sustained amount, we can move very quickly and meet our goal of vaccinating this high-risk population.

Senator HIRONO. So, Dr. Stone, you have a capacity to vaccinate a lot more people than the number of doses that you get. What is your capacity right now?

Dr. STONE. Capacity right now is in excess of 300,000 a week. I mentioned that over the holiday weekend we were able to do over 70,000 a day. I think that is sustainable. And so, therefore, somewhere between 350,000 and 600,000 a week is certainly within the realm of possibility.

This is one of the most effective vaccination programs ever, remembering that nobody has tried to do this since the Sabin and Salk vaccines of the 1960's in the polio epidemic in the children of America.

Senator HIRONO. Yes. So did you say that you get 125,000 doses per week, that is currently what you are getting now?

Dr. STONE. We were just called on the way over here to say that we would be getting about 500,000 doses this coming week. We have seen a gradual increase, and we are very hopeful with the

new vaccine that is coming on the market that we will continue to see increases, and the problems that we are having with the amount of vaccine will resolve itself over these next number of weeks.

Senator HIRONO. So you are getting 500,000, and your current capacity is 300,000. Are you opening up other PODs outside of the VA system to provide these vaccines?

Dr. STONE. We will expand our VA direct delivery system to accommodate this. We are very efficient at it. We also have, through our Community Care, offered through our urgent care system, vaccination if those are urgent cares were able to get vaccine. And so we will continue to increase our capacity as we receive additional supplies.

Senator HIRONO. So you can do this all within the VA system, is what you are saying.

Dr. STONE. Yes.

Senator HIRONO. So you did indicate that you are vaccinating first the people who are in your system. So there must be a lot of veterans who have never utilized veteran services. But at some point you need to contact them, right?

Dr. STONE. We are reaching out to veterans and asking veterans. We have had over 8 million contacts the last few weeks, where we have reached out to veterans and encouraged them to enroll in VA health care. Both Mr. Gigliotti and Dr. Patterson can discuss their efforts in enrolling veterans on the spot who come in for vaccination.

Senator HIRONO. I am running out of time, so I originally asked what is your target number and you did not give me the number. You said 6 million currently in the system. But how many veterans are out there?

Dr. STONE. There are 18,500,000.

Senator HIRONO. And your goal should be to get every single one of them vaccinated, assuming that they are not going to object to getting a vaccine. So I know that you are doing everything you can to reach out to all of the veterans who are not within the system right now. Have you seen that during this COVID that there are veterans who have not utilized veteran services who are contacting you on their own because they want to be vaccinated?

Dr. STONE. Yes.

Senator HIRONO. Good. You have been asked a number of questions about vaccine hesitancy, and I think you said that you have not seen that—I may have heard this incorrectly—you have not seen this in communities of color, vaccine hesitancy. Did I hear that correctly?

Dr. STONE. You did. We are actually very proud of the jobs that the team has done to reach out to communities of color, to improve their trust and confidence in both the vaccination program and the VA.

Senator HIRONO. So there is just one more quick thing, if you do not mind, Mr. Chairman. I do appreciate that the VA is providing vaccines to veterans in Guam and American Samoa. I understand the rate of vaccination among these veterans is really low, with only a handful of veterans in these places being vaccinated so far. I hope that you are making concerted efforts to reach out to the

veterans in Guam and American Samoa. They often have difficulty getting access to veteran services. That is my understanding. So there are logistical challenges to them getting the vaccines, that I hope you are addressing these challenges, Dr. Stone.

Dr. STONE. Senator, I will tell you, this has been a very frustrating area. We have been working through the Departments of Health at each of these areas. We have agreed to bring in additional personnel to support those Departments of Health. We need the Departments of Health, primarily because of the refrigeration capacity, and we are looking forward to the newer vaccines as they come that do not require as complex handling, to expand our ability to reach each of these islands and areas.

Senator HIRONO. Thank you. Thank you for doing your very best. Thanks, Mr. Chairman.

Chairman TESTER. Thank you, Senator Hirono. I want to recognize one of the two new members to the Senate Veterans' Affairs Committee, next, Senator Tuberville. And we have all been waiting anxiously for your questions.

SENATOR TOMMY TUBERVILLE

Senator TUBERVILLE. Thank you very much, Mr. Chairman. Thank you for what you do. I am a military brat. Dad died on active duty. Huge. I spent a lot of time in the VA over the years with my dad. But as a representative of the State of Alabama we have 380,000 veterans. We are a military State. And I just recently went through most of our VAs through the State, and I am very proud of what they are doing. Obviously, we have got a lot of work to do in some areas. but we have got a lot of veterans, and with these wars that we have had we have got a lot more coming. And all veterans need a vaccine. They all need it. We all know that, and we are talking in circles in here, in some areas.

There are a lot of new veterans in our State that have PTSD, underlying conditions. And I know that we want to get it to the older veterans, and rightly so, because they are more vulnerable. But nobody is any more vulnerable than our kids, our young men and women with PTSD, and we have got a lot of them. We are losing 22 veterans a day to suicide, and that has really increased since this virus, because stacking one problem on top of another creates more problems.

And I really do not have a question. I just wanted to ask you, really, is there any priority to any of these young men and women that have recently come back, you know, with PTSD, with underlying conditions, with lost legs, lost arms, that have huge problems on top of problems, and scared to death that they are going to get this virus but they cannot get the vaccine. Is there any priority that we can look at that?

Dr. STONE. There is, sir, and it is part of that 1c group that Dr. Kim was talking about, as we have looked at it. Now we have not seen an increased amount of virus sensitivity based on PTSD, but we have seen a lot of problems, and those problems primarily relate to the intense isolation that has occurred because of this pandemic and the fact that people have been locked in their homes.

Therefore, we have converted about 75 percent of our behavioral health engagement to video-type visits that have reached into the

veteran's home, and we have replaced face-to-face visits with video visits that a veteran can interact with our psychiatrists and psychologists to make sure they remain stable.

Our calls to our Veteran Crisis Line have gone up very significantly. Part of that is the 988 system that is being fielded around the Nation. But the rest of it is because of the really strain on this population that you so articulately laid out. This is an extraordinarily at-risk population that needs our engagement.

Senator TUBERVILLE. Thank you very much. Another thing that I noticed—and not just going through the VAs but also the hospitals all over Alabama—we are struggling, at times, even getting first responders to take the vaccine. They are a little leery about taking it. Marketing is a huge problem sometimes, in something new like this. I wish, you know, with the trillions of dollars, billions of dollars that we are spending on this, sometimes you need to market, you know, through public service of take the vaccine. We have got to get rid of this thing. I mean, and people do not take this if they are leery of it.

Sometimes you even use football coaches. In our State we have got a pretty famous one in that State that probably could do a PSA to say, "Take your vaccine. First responders, veterans, anybody that has an opportunity to take it." I think sometimes we forget to use the things that we have at our disposal to get people to understand that, you know, things do work, and we are not trying to trick anybody. We are just trying to make it work.

But again, thank you for your service. Thank you for what you are doing. We truly—and I know our veterans appreciate it too. We truly thank you. Thank you very much.

Thank you, Mr. Chairman.

Dr. STONE. Senator, thank you. Let me just respond that anybody that a veteran trusts, that can talk about this vaccine, has value to making sure that we increase the amount of vaccination. Your State has some of the lowest acceptance rates of vaccine in the country, and part of that dates back to World War II era, where there were some egregious things done in various experiments. So that message needs to be overcome, and we would welcome participation in that, to get that message out.

Chairman TESTER. Thank you, Senator Tuberville, and I am sure the football coach you are referring to is the old Auburn Tiger himself, Coach Tuberville.

Senator Blumenthal?

SENATOR RICHARD BLUMENTHAL

Senator BLUMENTHAL. Thanks, Mr. Chairman. I apologize if I cover ground you have already done, but I first want to say how proud I am to know that Connecticut, really, I think it is at the forefront of these efforts to vaccinate veterans. In Connecticut, 47 percent of our veterans have received a first dose, and 23 percent a second dose, which is far ahead of the national average. I am also pleased to say that 77 percent of our veteran employees have been vaccinated, and so they are protected.

I think that this kind of record is due to real leadership. Obviously, you are trying to inspire that kind of leadership at the national level. But we need more aggressive leadership at the local

level to counter the kind of misinformation and hesitancy that is found among certain populations, and, as well, to provide vaccinations to caregivers and spouses, family members, who live with our veterans, because I think one of the reasons why veterans may not come for a vaccine is that their spouse or caregiver is not going to get it as well, and either because they depend on that person for transportation and advice or for some other reason, they may be hesitant.

I know you have answered the question about what can be done to provide the vaccine to those caregivers, the non-veterans who provide for our veterans, and that you would need additional statutory authority to do so. Is that correct?

Dr. STONE. For the most part, yes. It is a bit of a nuanced answer and I apologize for that. For those families that are engaged in our subsidized or reimbursed family caregiver program, that caregiver program we do have authority to give vaccine, and have vaccinated more than 2,000 family caregivers. What we do not have authority for is the rest of the population that are not on subsidies, and in those subsidies—and it is a nuanced, complex answer and it is not very satisfactory, sir. We need some additional authorities to get to the rest of that population.

We have 200,000 elderly, frail veterans that we are helping in the home. About 20,000 we can vaccinate their caregiver, and 180,000 we cannot. And that is the kind of discussion that we need to have of how we get those additional authorities in order to protect that veteran and their caregiver.

Senator BLUMENTHAL. Well, I offer my support and help. Whatever we can do to expand that authority, if necessary, I think there would be strong support for it.

And as to the younger veterans, are they more hesitant? Are they less likely to take the vaccine? Do you notice any difference in age groupings as to that hesitancy?

Dr. STONE. I am going to defer to Dr. Kim on this.

Dr. KIM. Yes, I will maybe speak to the focus group that we did with veterans, that included veterans of younger and older age, and I think what we saw, you know, I think reflects maybe what we see in non-VA surveys from last year, is that hesitancy is at all age groups, unfortunately. I think it falls along racial and ethnic lines, actually, where blacks and African Americans and Hispanics had more hesitancy compared to whites, and that was played out by age. And I know it was a focus group, but I think it just really parallels what we see in larger national surveys.

So I think our efforts to communicate really reach across ages, to make sure that we get the messaging across about the science, that we can trust these vaccines, that they are safe and effective.

Senator BLUMENTHAL. And then, finally, if you had to pick, out of a community, one person, one type of person to overcome that hesitancy, to recruit people to take the vaccine, would it be a faith leader? Would it be a coach? Who would you choose?

Dr. STONE. It would be your provider, your nurse practitioner or your PA or your physician.

Senator BLUMENTHAL. So someone with medical credentials——

Dr. STONE. Yes.

Senator BLUMENTHAL [continuing]. to talk about medicine. Makes a lot of sense, right?

Dr. STONE. And, sir, that is exactly why we think we have done so well with this, is we have had this proactive outreach to our communities, especially our communities of color, and we think that is why we have erased the disparities in the population, that other parts of the American health care system are seeing. And we are trusted, because of what Dr. Patterson said. We are trusted because we are in those communities.

Senator BLUMENTHAL. And again, the people who are most persuasive and compelling on an issue of science or medicine are the people who have the credentials of medical doctors or nurses or scientists, who can attest to the efficacy and safety of the vaccine.

Dr. STONE. Yes, sir.

Senator BLUMENTHAL. Thank you. Thanks, Mr. Chairman.

Chairman TESTER. Thank you, Senator Blumenthal. Senator Sinema.

SENATOR KYRSTEN SINEMA

Senator SINEMA. Thank you, Mr. Chairman, and thank you to Ranking Member Moran for holding this hearing, and thank you to all of our witnesses for being here.

Dr. Stone, I appreciate that in addition to providing vaccine support for its work force, the VA has stepped in to support vaccine distribution for the Department of Homeland Security. This is an especially important program for Arizona's Customs and Border Protection employees.

In Arizona, the VA should further identify ways to offer vaccines for CBP employees through VA community clinics and mobile vet centers, given the often long distances between where they work and the nearest VA medical center. You know, it is 3 hours from Yuma, on the border, to our medical centers in Phoenix or San Diego, and it is 3.5 from Yuma to Tucson. So I would appreciate you and your office keeping me updated as you work with DHS to expand this program, and share any challenges you experience.

We have heard from a number of Arizona veterans with questions and concerns about the availability of the vaccine and scheduling appointments across the Arizona VA medical centers. I appreciate the responsiveness of the Arizona VA medical centers as my team works at the local level to address these concerns. So I will focus my questions on how these issues are being addressed nationally.

Currently, the VA has 9.3 million enrolled veterans, 6 million with an active status. We have received calls from veterans who enrolled with the VA, have an inactive status, and are scheduled and then canceled, presumably because of their inactive status. Should veterans with an inactive status have access to vaccination appointments, and if so, what clarifying guidance must be sent to the medical centers to make sure that they do?

Dr. STONE. When we are no longer in an austere environment where we know that we are only going to get 6 million doses, I think will be able to expand to the rest of the enrolled but not active users.

Senator SINEMA. So there will be a point where the VA will be able to offer vaccines to inactive status veterans.

Dr. STONE. That would be my absolute desire. You know, my view is that none of us are going to get our lives to turn back right-side up again until we get the American population vaccinated. So I share your desire to get vaccine into as many people as we can. And as soon as CDC and HHS can assure us that we will move beyond the 6 million doses, we will expand, and we are actively recruiting veterans to move to enrolled status so we can begin to interact with them.

Mr. Gigliotti, I think, can discuss some of the efforts in his VISN, as can Dr. Patterson in his VISN, to really seek out those veterans and to bring them in.

Senator SINEMA. Well, thank you. My next question is, how is the VA tracking instances of canceled vaccination appointments to ensure that veterans are not losing access, and how are they identifying and fixing potential problems as they arise?

Dr. STONE. Mr. Gigliotti or Dr. Patterson, do you want to take that?

Dr. PATTERSON. Senator, what we do is reschedule them. So if they call in and cancel and cannot make the appointment we usually ask them why, just to be sure that, for instance, they are not ill and maybe they need to come to the clinic anyway. But we just put them back on the list and reschedule them.

Senator SINEMA. Okay. Do folks fall through the cracks when that occurs, or is that not something you have experienced?

Dr. PATTERSON. You know, it is really interesting when I visit the medical centers and see the vaccination clinics, the incredible enthusiasm that the staff has. It is really rewarding to go and watch how eager they are to vaccinate people. So they have a list and they keep up with it. I cannot guarantee that nobody falls through the cracks, but clearly they want to get them vaccinated.

Senator SINEMA. Thank you. Moving on, the Northern Arizona VA Health Care System is piloting the use of a mobile vet center to bring vaccines to community clinics in an effort to expand distribution to more rural areas. This is very important for vaccinating Arizona veterans. What is the VA doing nationally to ensure that as efforts such as this expand access to rural and highly rural areas, how is the VA working to ensure that these are successful, that they are resourced appropriately across the VA network, so that rural and highly rural veterans can also access the vaccine?

Dr. STONE. So Mr. Gigliotti, in his VISN, piloted an airborne delivery of vaccine. We have now expanded that to VISN 20 in both Alaska and Oregon. We also are using mobile assets, as you referenced, and we are discussing these type of unique solutions on a daily basis, in what we call our health operations update, where each of the VISNs highlights what they are doing to get vaccine out.

We have been having ongoing discussions with our emergency operations team to make sure we have maximum numbers of vehicles available and have been working with the White House team to assure that we are taking what I view as the most difficult area of inequity, which is the remote areas of this Nation where there are health care deserts, trying to get vaccine into areas.

We are very proud that last week we flew an airplane into southern Alaska to an island where there were 50 veterans, and vaccinated virtually the entire veteran population. It is that kind of creativity and effort that I describe as part of the herculean effort that we are undergoing. Nobody has done this before, but one of the things we have recognized is these huge distances and remote areas, especially as you have described, in your State.

Chairman TESTER. Thank you, Senator Sinema.

Senator SINEMA. Thank you.

Chairman TESTER. Next up we have the second newest member, or one of the two newest members, I should say, from the great State of New Hampshire, Senator Hassan.

SENATOR MARGARET WOOD HASSAN

Senator HASSAN. Well, thank you very much, Senator Tester and Ranking Member Moran, for holding this hearing on what is a critical issue of vaccine distribution to veterans. And I just want to say I am really excited to be a member of this Committee and I am really looking forward to the work that we can do together to serve our veterans. And I want to thank the witnesses today for your work to serve our Nation's veterans too.

Dr. Kim, I wanted to start with a question for you. First, thanks for working to get these vaccines out to veterans as quickly as possible. New Hampshire, as you probably know, does not have a full-service VA hospital, and as a result, Granite State veterans get some of their care across the border at the VA Medical Center in White River Junction, Vermont, or in Bedford, Massachusetts. That can create some challenges when the States are not fully aligned in terms of vaccine availability and protocols.

So how does the VA determine the vaccine allocation for these kinds of facilities that serve veterans across State lines, and what steps is the VA taking to disseminate the information to veterans who may be crossing State lines to get their care?

Dr. KIM. Sure. So I think, Senator, that the answer to that question is that we know for the veterans who receive care in a certain medical center who they are. We know their age, their demographics, et cetera. So whether they live in New Hampshire or whether they live in Massachusetts, if they are served by that medical center or clinic we know whether they are in a priority phase for vaccination.

So we will reach out to them, regardless of where they live. I have patients who I see in North Carolina but they live in Virginia. To me that does not matter. They are served by me so I will reach out to them when it is their turn. And I think the same would apply to your veterans, as well, in your State.

I wonder if, you know, the question is whether—you know, I know each State has their own phase where they are. Certainly each State has flexibility to do that. For the VA, you know, we do follow CDC, but there is flexibility, say, for your area of the country, for that particular VA to move into Phase 1a, 1b, or 1c, depending on how much supply they have. But it really depends on the veterans they serve in that facility as to, you know, when they are reaching out to them.

Senator HASSAN. Thank you. Another question for you, Dr. Kim. Many facilities are offering an online appointment registration system for veterans to sign up for the vaccine, and if this has been asked already forgive me. But the online portals are obviously a great tools. Some veterans may struggle with the technology, though, or they do not have the connectivity to access the system. And many veterans in my State live in rural areas, which, one, has less access to broadband. Also a lot of veterans in my State are older and have less exposure to online tools.

So what alternatives is the VA offering veterans who may have limited internet access or technological know-how to register for appointments online?

Dr. KIM. Sure. I will just say—and I will let Mr. Gigliotti and Dr. Patterson comment—we are using all modalities, especially those we know that are veterans in each medical center respond to.

Senator HASSAN. Thank you.

Mr. GIGLIOTTI. Senator, in that scenario, the partnership with American Legion, Disabled American Veterans, and other service organizations is critical to get the word out. One thing we have also had great success with are electronic town halls. They have really ramped up in the last year, due to the pandemic. The minimum attendance that we have had is 1,500, and in some cases up to 8,000. So veterans getting the word to other veterans has also really helped in that scenario.

Dr. PATTERSON. Yes, Senator. The veteran service organizations are a great partner in this way. We reach out to them, ask them to contact their members, and they will also contact other people in the community, even if they are not a member of the VFW or the Legion. And we are using some of their facilities, because it is a great drawing point.

Senator HASSAN. Thank you. I will just echo what Senator Sinema was just speaking about, in terms of making sure we are getting to our rural veterans in remote areas. And it was great to hear the pilot programs you have up in Pittsburg, New Hampshire, which is on the Canadian border. It is one of our largest towns but it has 900 people total, and it is a beautiful spot but it takes 3 hours for people in wintry weather to get to Manchester. So I really appreciate those efforts and would like to work with you all on expanding them.

Dr. Stone, I wanted to drill down a little bit on the data you have about veterans who are declining the vaccine. We have begun to see data on the rates of certain segments of the population declining to get the vaccine, including actively serving military members and first responders, something that you have heard about from other members of the Committee too.

In your testimony you described listening sessions with minority veterans and other concrete steps that you are taking to help reduce vaccine hesitancy among the veteran population. Now that vaccines are being administered, are you gathering data on how many veterans have declined to receive the vaccine and whether their reasons match the concerns you were hearing about during your planning?

Dr. STONE. I do not think our data is as clear as it should be, and it appears that about 15 percent of the population is declining.

And then as time goes on much of that is just a hesitancy, that once their friend begins to get it, or a fellow veteran, or a family member does, they will then go ahead and get the vaccine. So the numbers are declining of hesitancy, but it requires very active listening sessions and engagement of that population in order to resolve it.

I will tell you, I have worked the vaccine clinic that we have been operating in Washington, DC. Many of the people coming in, especially in the communities of color, want pictures taken so they can send it to their family members, say, "Look, I got the vaccine." It has been a very emotional engagement, even as a provider with 40 years of experience. These are very emotional engagements for many of these families. But it is those kinds of things that we have been talking about that I think has made us successful in erasing a lot of the hesitancy.

Now there is a portion of the population that will never get the vaccine, and we have seen that with vaccine, really, refusal across many areas of the country, over multiple types of vaccines. This is really unique, new types of vaccines that we are dealing with, and it is just going to take a lot of education and a lot of work and a lot of trust for us to get to where you and I would like to be one this.

Senator HASSAN. Thank you very much. Thank you, Mr. Chair, for your indulgence.

Chairman TESTER. Thank you, Senator Hassan. A couple more questions, really quick. First of all, just to followup to Senator Hassan's question, I think gathering that information as to why the veterans are hesitant is critically important. You are spot-on on rural veterans. I think the Ranking Member would concur that there is a lot of hesitancy in rural America and we have got to figure out how to break that down.

Mr. Gigliotti, you are using fly ins to reach rural veterans, and you talked about expanding that to VISN 20, at least Dr. Stone did. I think it is really good. I think the fly ins can be incredibly effective, and they have been incredibly effective. The question is, are there other approaches you plan to use, because the fly ins are a bit limited.

Mr. GIGLIOTTI. Thank you, Mr. Chairman. We are using the fly ins, as you said. Today is our third one. Lewistown is having that. We are using dual-use vehicles and the medical mobile units, where we have them across our VISN, and those are part of the deployment strategy to reach the rural veterans, particularly in the rest of Montana, Wyoming, and we are looking at eastern Utah for that. So those are critical.

Dr. Patterson made the point, in his VISN, which is accurate for mine, that 90 percent of our VISN population of veterans lives within 60 miles of a facility that can give out the vaccine, and a large chunk of that percentage is within 0 to 30 minutes, and then 30 minutes to 60. So it is really going to be important for us, when the volume increases in the vaccine, to get the word out, to be able to come to those clinics themselves, and for those very rural areas using those two vehicles, the flights as well as the dual-use vehicles.

Chairman TESTER. Yes, and it all works together. You guys know that. I mean, the availability of the vaccine is No. 1, so you guys can plan for it and tell the folks where to go, to those CBOCs, or whether there is a mobile van going out and how to get to them. So I appreciate that.

Dr. Stone, what percentage of the work force has refused the vaccine?

Dr. STONE. I can tell you that 73 percent of the entire work force has received the vaccine, over 90 percent of our clinical personnel. Refusals of the vaccine have primarily occurred amongst some of our non-licensed personnel in our CLCs, and we are working hard to do educational programs for that in order to get those numbers up.

Chairman TESTER. As a last resort, do you have the authority to make the vaccines mandatory as a condition of employment, regardless of whether these are medical professionals or they are non-licensed personnel?

Dr. STONE. Senator, I have that authority but I am not going to use it, and I am not going to use it under the Emergency Use Authorization. When there is full licensure of the vaccine we will revisit that decision, but as an Emergency Use Authorization, and the fact that our employees are dramatically taking the vaccine. This is much different than the commercial marketplace. Our employees are taking the vaccine, and I am very pleased. That has been reflected in the fact that prior to the vaccine we were running consistently 6,000 employees that could not come to work because of either exposure or actual infection with COVID. That number this morning has dropped to under 1,100. So literally 5,000 more people are coming to work now than had.

Chairman TESTER. Senator Moran.

Senator MORAN. Senator Tester, thank you for the second round. I will try to be brief, as you were. I want to ask a few questions related to the $17 billion request for the VA making its way through Congress. In my view, unfortunately, it is coming through Congress in an expedited manner, that we will not have, as this Committee, the opportunity to debate and amend, or even understand that legislation.

I want to visit with you about how the request is related to the $10.5 billion that is remaining in the CARES funding currently. Is it true—I think you said this, maybe in your opening Statement—is it true that the remaining $10.5 billion in CARES funding will met COVID-specific needs, such as PPE, testing equipment and supplies, increased health care costs, through the remainder of the fiscal year?

Dr. STONE. It is my anticipation that it will meet the requirements primarily of health care. About $3.5 billion is needed for Community Care, and we have a request that is working its way through to repurpose $3.5 billion in Community Care. The majority of the rest will go into direct patient care, within our direct care system, for the care of patients with COVID.

Senator MORAN. So $10.5 billion, about $3 billion of it needs to be repurposed to meet Community Care opportunities, requests, and the other $7.5 billion is to provide care within the VA?

Dr. STONE. The financial people are probably cringing at this point because I am sure there is a piece that I have missed. There are some pieces that are going into the homeless programs. We have taken the caps off of HUD-VASH vouchers to make sure that we are taking away insecurity in homes. But that is primarily what it is addressing.

Senator MORAN. And then the $17 billion that is in what I would call Phase 5, the legislation that the House is currently considering, those are targeted at needs that may occur in Fiscal Year 2022 and beyond, and in part, at least based upon pent-up demand for health care?

Dr. STONE. I would not quite put it that way. I think it will be late 2021 that that occurs. I think probably the last quarter of 2021 we are going to see a bow wave.

Let me give you an example of this. We are down by 12,000 surgeries a month in our direct care system. They are not going out to the community. That is pent-up demand and it is surgery being done later. Think about putting off a knee replacement for a year. That is a tougher surgery. And so what our actuaries are telling us is that deferred and delayed care is going to create a bow wave that none of us anticipated a year ago, when we were looking at what was in the CARES Act.

In addition, reliance on our system that is coming because people are losing insurance because of job loss is resulting in more veterans enrolled. We will enroll well over 300,000 additional veterans this year. And so that sort of bow wave is what we are trying to take care of in this late 2021 and 2022 timeframe. It is our hope, then, that that will stabilize once we have taken care of that, and we can come back here with a much more optimistic picture.

Senator MORAN. Dr. Stone, you would not expect me not to ask this question. The reason that I want to make sure I understand—you also said it is not occurring in the community, under Community Care, it is not occurring in the VA, the surgeries that you described. The fact that it is not occurring in Community Care is not a result of anything that the VA is doing to restrict that from occurring in the community. It is just that the patients are deciding to defer. Is that true?

Dr. STONE. The best example of this is the fact that we have got a big problem in VBA, where we have got people that do not want to come in for their comp and pen exam. So we have got a lot of built-up comp and pen exams. Over 50,000 of those are veterans that just will not come in for a face-to-face visit. Well, if you will not come in for your comp and pen exam, you are not coming in for your knee replacement either.

And so it is not because we are failing to refer to the community or have not built an adequate community environment for people to go to. This is exactly what happened after the great influenza of 100 years ago, that there was this bow wave of care that was necessary because it was delayed or deferred.

Senator MORAN. Dr. Patterson, anything unique about our VISN in regard to this topic?

Dr. PATTERSON. No, Senator. There is not.

Senator MORAN. Okay. Thank you. Just to conclude, Mr. Chairman, first of all, Dr. Patterson, is there anything that you would—

I do not know how many times you have testified before Congress, but welcome to this occurrence. Is there any request that you would have of me on behalf of the veterans in our VISN, that you would like for me to know?

Dr. PATTERSON. Well, Senator, I know you visit every county every year, and I really appreciate it when you come visit our vaccine clinics, because it is great press for us. It hits the local news, and I think it just encourages veterans to come in and get vaccinated.

We have a rally cry in our network called "Reclaim the Summer," and you might have heard that when you were in Topeka earlier this week. But that is what we want to do. We want everyone vaccinated so we can have a summer again, play baseball.

Senator MORAN. I like that. In the absence of the Chiefs' victory maybe we will have a Royals victory.

I would add to only confirm what Senator Blumenthal said, and that is the importance of spouses and caregivers. And yesterday Senator Tester and I, in our conversations with the general and the doctor, General Perna and Dr. Kessler, raised this issue with them, and they indicated a willingness to see if there was something they needed to do to make this possible.

I did not understand your response to Senator Blumenthal. Is there something that prohibits the VA from vaccinating spouses, spouses who are not veterans?

Dr. STONE. Yes.

Senator MORAN. Okay. And that could be corrected within this system that we have developed for distribution of vaccines, or takes something within the VA, within the Congress?

Dr. STONE. Not within the authority of the Secretary to do non-veterans for providing any sort of health care, unless they are on the stipend program.

Senator MORAN. Maybe there is a way to get to it in the fourth mission. I will look for ways to be of help in accomplishing that.

Dr. STONE. Sir, we are talking to a number of States about exactly that, and working with a number of States to try and get at it in that manner, and thus unload the rest of the State from the vaccine that is necessary and protect veterans at the same time, sir.

Senator MORAN. That is good news. Mr. Chairman, thank you.

Chairman TESTER. I will tell you this, Ranking Member Moran. Our staffs are going to get together and we are going to figure out what kind of language it needs to give them the temporary authority in this particular case of a pandemic, and then we are going to give all the credit to Boozman. That is just the way it works around here.

I just want to thank you guys for your testimony. I am going to give you an example of exactly what you are talking about on pent-up demand. My brother, who is a few years older than I am, that has COPD, has not seen a doctor in a year. He just got his second shot. He is proceeding to set up doctor appointment after doctor appointment after doctor appointment right now. There is a lot of pent-up demand out there, and there will be. You guys being able to deal with that is going to be a challenge.

The other thing we have not talked about here today, that we all know is a big deal, is mental health, and the fact that the isolation caused by this pandemic has only contributed, not only in the VA but across society, to increased mental health problems. I just met with a bunch of school personnel today that are talking about kids having increased mental health problems.

I will just put a plug in for the John Scott Hannon bill, that the Ranking Member and myself got done last Congress. I think that can help, and, of course, telehealth can. But that is another expensive proposition that we have to deal with. Thank God you are there, Dr. Stone, and you have good people like the panel up here today, that can deal with that.

Look, I cannot give you guys enough credit. The Ranking Member and myself were on the call yesterday with Dr. Kessler and General Perna, and, quite frankly, we just need to get more vaccines in your hands to get distributed. I think what happened today is a really good sign, and hopefully that will keep up. And they assured us that, by the way, it would come up, that it would ramp up more and more. And, in fact, in 3 weeks it sounds like you guys may be really in full swing.

So thank you for what you are doing. We are going to continue to push the administration in a bipartisan way to use all the authorities they have to get more doses allocated for the VA. It is important that we take care of our veterans. It is a cost of war.

I would ask that any post-hearing questions be sent to the clerk no later than a week from today, and we will keep the record open for a week as well.

This hearing is adjourned. Thank you all.

[Whereupon, at 5:49 p.m., the Committee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

STATEMENT OF
RICHARD A. STONE, M.D.
ACTING UNDER SECRETARY FOR HEALTH
VETERANS HEALTH ADMINISTRATION (VHA)
DEPARTMENT OF VETERANS AFFAIRS (VA)
BEFORE THE
SENATE COMMITTEE ON VETERANS' AFFAIRS

February 24, 2021

Good afternoon, Chairman Tester, Ranking Member Moran and distinguished Members of the Committee. Thank you for the opportunity to testify today about the Department's response to the Coronavirus Disease 2019 (COVID-19) vaccine rollout. I am accompanied today by Mr. Ralph Gigliotti, Director, Veterans Integrated Service Network (VISN) 19, Dr. William Patterson, Director, VISN 15 and Dr. Jane Kim, Chief Consultant for Preventative Medicine.

In December 2020, the Food and Drug Administration issued Emergency Use Authorizations for two vaccines, one manufactured by Pfizer-BioNTech and the other by Moderna, for the prevention of COVID-19. The Centers for Disease Control and Prevention (CDC), with guidance from the Advisory Committee on Immunization Practices (ACIP), issued recommendations for use and for phased allocation of vaccine when supply is limited. Immediately after, VA began offering vaccine at VA facilities.

VA COVID-19 Vaccine Distribution Plan

In September 2020, VHA chartered a team to plan for the availability of a COVID-19 vaccine as early as October 2020. This team, composed of key offices within VHA to include National Center for Health Promotion and Disease Prevention, Pharmacy Benefits Management Service, Ethics and Logistics and Office of Healthcare Transformation, working with CDC, developed a comprehensive plan to ensure availability of a COVID-19 vaccine across the VA system as they become available. The distribution plan addresses vaccinations for Veterans, staff and other Federal partners including a framework for identifying the population(s) at highest risk from COVID-19 to receive the vaccine. This risk stratification aligns with the ACIP's and CDC's recommendations for allocation of COVID-19 vaccines.

VA's plan is based on five core ethical pillars: safety, maximizing the benefit of the vaccine, equity, fairness and transparency. VA offered the vaccine to health care personnel as they are essential to continuing to care for patients throughout the pandemic and Veterans living in Community Living Centers and spinal cord injuries and disorders units where the risk of severe illness and death due to COVID-19 is highest.

VA's COVID-19 Vaccination Plan provides a framework for facilities in administering their local vaccination plan, but specific logistics and processes vary by

facility. VA facilities are reaching out to Veterans when they are eligible, and Veterans are encouraged to use the Keep Me Informed tool to sign up for updates about VA vaccination in their area. VA's ultimate goal is to have enough vaccine to vaccinate all Veterans and health care personnel who want to be vaccinated.

Administration of COVID-19 Vaccines

As of February 11, VA has administered over 1.5 million doses of the COVID-19 vaccine. This includes over 1 million doses to Veterans, 458,000 doses to VA employees and over 6,100 to our sister Federal agencies, mostly the Department of Homeland Security (DHS). VA is reporting that information publicly on the Department of Veterans Affairs COVID-19 National Summary: https://www.accesstocare.va.gov/Healthcare/COVID19NationalSummary. In January, through an interagency agreement to support DHS's COVID-19 vaccination program, trained VA medical professionals at certain VA medical centers began vaccinating DHS employees using DHS's CDC vaccine allocations. Twenty-one facilities are currently offering DHS vaccinations. Overall, VA is currently providing vaccines at more than 215 sites nationally, with plans to expand to additional sites as vaccine supplies increase.

In collaboration with each of VA's 18 VISNs, VA's Pharmacy Benefits Management Service determines vaccine allocations for each VISN within VA's total allocation from the Department of Health & Human Services (HHS). VA's current vaccine allocation is distributed to VISNs pro-rata, with the basis for the current pro-rata allocation being the proportion of Veterans who fall in CDC Phase 1b, the majority of whom are 75 and older Veterans. The numerator is Veterans who have had VA health care in the past 12 months in each VISN who are 75 and older. The denominator is all Veterans who have had VA health care in the past 12 months in our entire system who are 75 years and older. HHS follows a pro-rata approach to allocate vaccine to Federal entities, states and jurisdictions. VHA also utilizes a pro-rata approach for distribution of our allocated supply to sites across the country based on the number of Veterans who are in CDC Phase 1b, which is the phase where the majority of our sites are currently.

To provide the vaccine to as many Veterans as possible, VA planned mass vaccination clinics at VA facilities across the enterprise. In Salisbury, North Carolina, VA administered nearly 500 vaccines to Veterans aged 65 and older or those who have high-risk conditions. In West Palm Beach, Florida, nearly 600 Veterans were vaccinated by appointment. Lexington VA Medical Center held a 3-day mass vaccination event and administered vaccine to over 4,000 Veterans who were 50 and older. Most recently, the Montana VA administered vaccine to nearly 9,500 Veterans in Great Falls, Montana. Additional mass vaccinations will occur across the enterprise as supply allows.

In response to our leading the Nation in consumption of vaccine doses, VA received an increase of about 16,000 doses of the vaccine per week and recently also received an additional 200,000 doses that have been distributed as well. We anticipate using all of those doses as they arrive, and our current vaccination plan has the

capacity for delivering between 300,000 to 600,000 doses each week, so we are ready to accommodate and deliver larger quantities when they are manufactured.

In late January 2021, VA flew doses of the Moderna vaccine from the Montana VA Health Care System as part of a pilot program to provide vaccines to Veterans living in rural parts of the country. For this pilot, leaders at the Montana VA and VISN 19 worked to contract a charter flight to Havre, Montana while accounting for the special cold-chain requirements for distributing the vaccine. The initial pilot was successful, and lessons learned from that event were applied to the next rural vaccine event: a charter flight to Kalispell, Montana that occurred on February 3, 2021, and delivered vaccines to over 416 Veterans. Additional sites for flying in vaccines are being evaluated in Alaska and the Pacific Northwest. VA continues to explore several avenues for ensuring vaccines are delivered to rural Veterans where access and driving can be difficult.

To support those caregivers of Veterans participating in the Program of Comprehensive Assistance for Family Caregivers, VA offers COVID-19 testing and vaccinations to eligible family caregivers. Approximately 24,000 caregivers are eligible for COVID-19 vaccination in coordination with the Veteran they serve. VA used existing authorities to offer COVID-19 vaccination to primary and secondary caregivers enrolled in the PCAFC in order to protect this vulnerable population of Veterans and the caregivers who serve them. Some of these COVID-19 vaccinations may be offered in the home setting by clinical staff who perform clinical visits in-home to homebound Veterans and caregivers enrolled in PCAFC. Although current legislative authority does not allow vaccination of non-Veteran caregivers of homebound Veterans who are not enrolled in PCAFC, these caregivers are encouraged to pursue options for COVID-19 vaccination available through their local state or jurisdiction. More than 12,700 Veterans in VHA's Home Based Primary Care Program have received at least 1 dose of COVID-19 vaccine as of February 17, 2021, reflecting VHA's commitment to bring vaccination to these Veterans during the pandemic. These caregivers are offered appointments when their Veteran becomes eligible to receive the vaccine in accordance with the CDC guidelines and VA's phased risk stratification framework. Veterans and their caregivers can get the latest information and sign up to receive updates on VA's COVID-19 vaccine webpage.

VA is working hard to offer the vaccine to all Veterans receiving VA health care. All enrolled Veterans are eligible for vaccination when their local VA facility has sufficient vaccine supply for their risk group. The agency is focusing efforts on the allotment of vaccines we have received for enrolled, eligible Veterans who are listed in our highest risk categories. Veterans who are not yet receiving care through the VA health care system are encouraged to enroll now. In order to enroll, Veterans must meet certain eligibility requirements under current law, which may include income limits. Currently, VA does not have the legal authority to expand enrollment with the sole purpose of administering the vaccine. Additionally, while VA does have the legal authority to vaccinate Veterans who are not eligible for VA health care, the law requires that VA must receive reimbursement. However, VA is prohibited from charging any

individual for receipt of the vaccine based on VA's agreement with CDC for vaccines. We look forward to working with Congress and discussing the best path forward to ensuring we are able to vaccinate as many Veterans as possible.

Access for Minority and Rural Veterans

In order to reach our most rural Veterans, VA identified logistical challenges and concerns among rural populations from VHA staff and previously solicited responses from Veterans. VHA reviewed available data on factors driving rural Veterans' health decisions, reviewed ultra-cold storage capacity, conventional cold storage capacity, refrigerator capacity and population enumerations for staff and Veterans for larger facilities that were potential sites for receipt of initial - 70C and -20C vaccine shipments in vaccine administration hubs and determined average and maximum drive times from hub VHA facilities to smaller VHA facilities and Community Based Outpatient Clinics in rural areas. VHA identified locations with conventional cold storage capacity and ship-to status as first sites to receive -20C vaccine product, including many smaller facilities serving rural Veterans, developed distribution guidance to facilitate transportation of vaccines to rural areas and also updated policy to increase flexibility for use and storage of vaccines at smaller sites.

VA focused early on planning to ensure equitable access and distribution of vaccines to racial and ethnic minorities disproportionately affected by the COVID-19 pandemic. VA held listening sessions with minority Veterans in October 2020 and identified key concerns and themes include the need for meaningful, trusted, science-based information; access to vaccine at VA clinics, not just at main facilities; and trusted sources of information including primary care providers, other members of the VA health care team and other trusted Veterans. VHA collaborated with the CDC and Federal partners to coordinate and leverage strategies and materials designed for minority reach.

Perhaps most importantly, in many VAMCs, VA staff and providers are calling Veterans they serve to provide information about and schedule appointments for vaccination. This may help overcome barriers such as vaccine hesitancy and difficulties signing up on-line for vaccination that may be particularly large in minority communities. Consequently, we have not seen racial or ethnic disparities in vaccination so far. For example, among Veterans cared for by VA who are aged 75 and older, a group currently prioritized for vaccination, 25% of White, 28% of Hispanic, and 30% of Black Veterans have been vaccinated.

Conclusion

Veterans' health care is our mission, and we are committed to providing high-quality health care to all our Veterans during these unprecedented times. I am so proud of our efforts in response to COVID-19 and our distribution of the vaccine. This is an extraordinary example of what VHA is and what we will continue to be in the future.

Your continued support is essential to providing this care for Veterans and their families. This concludes my written testimony.

STATEMENTS FOR THE RECORD

Hearing Before the United States Senate Committee on Veterans' Affairs

Submission of Moderna, Inc.

February 24, 2021

Chairman Tester and Ranking Member Moran, thank you for the opportunity to provide an update on Moderna, Inc.'s ("Moderna") efforts to combat the COVID-19 pandemic. The collaborative effort to end this pandemic has made remarkable progress. We have also confronted new challenges and continued human suffering and hardship. We know that much work remains. This submission will update you on the status of Moderna's continued efforts to help stop this pandemic.

In November, Moderna announced that data from our Phase 3 clinical trial demonstrated a 94% efficacy rate against COVID-19 and a 100% efficacy rate against severe COVID-19. At this time, Moderna representatives spoke with officials from the United States Department of Veterans Affairs ("VA") so that we could begin the process of providing medical education for our vaccine candidate to military veterans. In December, after robust review, the Food and Drug Administration ("FDA") granted an emergency use authorization ("EUA") for our vaccine. Moderna representatives again contacted the VA to provide information for United States vaccination providers and recipients. This included information on our COVID-19 vaccine, the eligible population, vaccine ingredients, dosage, administration, storage and handling guidelines, as well as information that should be provided to vaccine recipients or caregivers.

By the end of 2020, we had delivered 17.8 million doses to the federal government. To date, we have delivered over 45 million doses of our vaccine, with tens of millions more at different stages of the production process. We are on track to meet our commitment to deliver 100 million doses by the end of March. We have doubled our monthly deliveries since late 2020, and we are aiming to double them again by April to more than 40 million doses per month. Based on this progress scaling up manufacturing, we recently agreed to move up our delivery timeline: we now are aiming to deliver a second hundred million doses by the end of May and a third hundred million doses by the end of July. The allocation of doses for the VA will be determined by the federal government.

This work could not be more pressing. The pandemic continues to have a devastating impact. Half a million people have died in the United States alone. Many more have been ill, some severely. As you all know, the pandemic has also cost jobs, shuttered businesses, closed schools, burdened families, and disrupted countless traditions and routines. All of us have been profoundly impacted by this. We also know that communities of color and essential workers have disproportionately borne the burdens of COVID-19. We must bring this pandemic to an end.

We understand the significant interest in Moderna's vaccine, along with the vaccines and vaccine candidates of other companies. We also understand how important it is that large quantities of every approved vaccine be produced rapidly—with robust commitment to safety and quality—and that vaccines be made available widely, transparently, and equitably. We hope

that this submission will provide useful information to this Committee as you continue your oversight over these important matters.

Over the past year, Moderna has been pleased to collaborate with the U.S. government in accelerating the development, production, and delivery of our vaccine. As we continue these efforts, we remain committed to ongoing dialogue with key U.S. government agencies to ensure that our work proceeds as quickly and safely as possible.

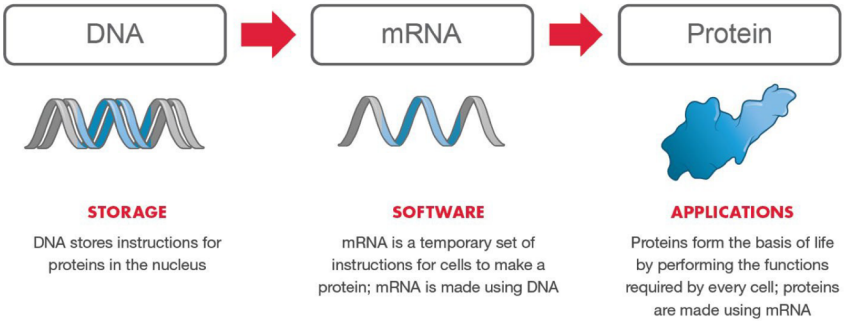
This submission will provide an update on Moderna's work. First, this includes a brief overview of our company and mRNA technology and an explanation of the process we used to create our COVID-19 vaccine. Next, this submission details the clinical trial process and the FDA's issuance of an EUA for our vaccine. Finally, Moderna submits to the Committee an overview of the manufacturing process and an update on our work to manufacture the vaccine.

Moderna deeply appreciates the opportunity to share this information with you, and we at Moderna are profoundly grateful for the actions you and your colleagues in Congress have taken to support and fund efforts to combat this pandemic.

I. Moderna is an Innovative Company That Has Built Unique mRNA Technology

Moderna is a young, innovative biotechnology company that seeks to improve patients' lives by creating a new generation of transformative medicines based on messenger RNA ("mRNA"). Founded in 2010, we are proud to be an American company, with our headquarters and a major manufacturing facility in Massachusetts. Moderna has grown over the past decade into a dynamic company with over 1,300 employees. This exceptional team—which has worked in collaboration with leading biopharmaceutical companies, U.S. government agencies, and private organizations focused on public health—has disclosed 24 therapeutic and vaccine development programs to date. These programs span a wide range of diseases and conditions, including infectious diseases, immuno-oncology, rare diseases, autoimmune diseases, and cardiovascular diseases.

At Moderna, we create medicines by using mRNA, which plays a fundamental role in human biology. All human genetic information is stored in DNA located in a cell's nucleus. In order to access that information, cells need to make a working copy of it—that is mRNA. Unlike DNA, mRNA molecules move out of a cell's nucleus; once outside the nucleus, mRNA molecules transfer the information they encode to the cellular machinery that make all the proteins required for life. Each mRNA molecule contains the instructions to produce a specific protein with a distinct function in the body. mRNA thus plays a central role in all biological processes, including in human health and disease, which is why we call it the "software of life."



Our approach fundamentally differs from traditional approaches to medicine. Rather than introduce a protein or chemical to the body, we send tailored mRNA into cells to instruct them to produce specific proteins. We built Moderna on the guiding premise that if mRNA can be used as a medicine for one disease, it could work for many diseases. Instead of starting from scratch for each new vaccine or therapy, our mRNA approach leverages the technology and fundamental components that we have been researching and developing since our founding. By building off our prior research and learning, we believe we can improve how we discover, develop, and manufacture medicines.

We designed our strategy and operations to realize the full potential value and impact of mRNA over a long time-horizon. Since 2010, we have built and invested in our technology platform, which creates mRNA sequences that cells recognize as if they were produced in the body. Our prior research and clinical trials taught us valuable lessons about designing vaccines—particularly how to manufacture and formulate mRNA that can be safely injected into people and induce an appropriate immune response. We believe this platform can be used to pursue mRNA medicines for a broad spectrum of diseases.

Creating a new generation of medicines is a challenging endeavor. Over the past ten years, Moderna raised over $5 billion in funding from our strategic collaborators and investors who recognize the potential of our unique mRNA approach. We are also grateful for approximately $58 million in grant funding from the Defense Advanced Research Projects Agency ("DARPA") and the Biomedical Advanced Research and Development Authority ("BARDA"). And in April, BARDA committed to fund up to $483 million to accelerate the clinical development and manufacturing scale-up of our coronavirus vaccine candidate. In July, we amended our agreement with BARDA to provide for an additional commitment of up to $471.6 million to support late-stage clinical development of Moderna's COVID-19 vaccine candidate, including the execution of a 30,000-participant Phase 3 study in the United States. In August, we signed a contract with the U.S. government to provide millions of doses of our prospective vaccine to the American people.

II. Moderna Used its mRNA Platform to Create an Effective COVID-19 Vaccine

Our mRNA technology is flexible and quickly adaptable; that allowed Moderna to step forward and pursue the rapid development of a COVID-19 vaccine candidate named mRNA-1273. We collaborated with the Vaccine Research Center and Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases ("NIAID"), a part of the National Institutes of Health ("NIH"), in January 2020 to try to accelerate our vaccine candidate.

The story of mRNA-1273 really begins before any of us had ever heard of COVID-19. Since 2015, Moderna has worked to develop mRNA vaccines for coronaviruses, such as the SARS and MERS viruses. And in 2016, we began building our U.S. manufacturing facility, based on our early clinical data, and our belief that the mRNA platform would be necessary to address diseases in the future. Those experiences, and Moderna's own proprietary technologies developed through years of research, put Moderna in a unique position to respond to the current pandemic.

For example, a key challenge in developing mRNA vaccines and treatments has been to develop a vehicle for getting the mRNA into the body's cell—in other words, the "packaging" for shipping the mRNA software into the cell. You need technology that both protects the mRNA in transmittal and will not be targeted by the body's natural defenses. After years of effort, Moderna has developed a proprietary lipid nanoparticle delivery system that enhances safety and tolerability. We have also invested significantly in the manufacturing process to invent the technological capabilities necessary to manufacture our potential mRNA medicines.

We were able to research and develop mRNA-1273 so quickly because we leveraged our prior research on vaccines and other mRNA-based medicines. In addition to the technology described above, this prior knowledge included our understanding of the safety of our platform and our experience producing over 100 batches of mRNA for use in human clinical trials in the two years before the COVID-19 virus emerged.

In our prior work on coronavirus mRNA vaccines, we identified a key protein on the surface of coronaviruses, called the Spike protein, as a good vaccine candidate. The identified Spike protein has two primary functions: (i) it facilitates the attachment of the coronavirus to the host cell in an individual; and (ii) it contributes to the entry of the coronavirus into the host cell by fusing viral and host membranes. We began to develop mRNA-1273 by reviewing the genetic sequence of the SARS-CoV-2 Spike protein. Based on the sequence for the Spike protein, we designed and synthesized a corresponding mRNA sequence—in other words, the genetic software that instructs a human cell to create the Spike protein. Using our validated mRNA vaccine platform, we have been able to formulate this mRNA by incorporating lipid nanoparticle technology into a vaccine that can be administered directly to a patient. Once injected, the mRNA molecule causes the patient's cells to produce the Spike protein; the body's immune system then attacks that protein, triggering a protective immunological response.

Our approach to a COVID-19 vaccine differs from traditional vaccine development because we are not injecting into the body a dead or weakened version of the novel coronavirus

or one of its components. Instead, we use the information from the virus to teach the cells in a patient's body how to make the virus's Spike protein, which itself provokes a protective immune response. Using this novel approach, we progressed from genetic sequencing to a vaccine ready for human testing in just 63 days—a testament to the 10 years of investment and hard work on our platform.

III. Clinical Trials Led to the FDA Emergency Use Authorization for mRNA-1273

Working closely with the government, Moderna put mRNA-1273 through a rigorous set of clinical trials to test its safety and efficacy. This process began extraordinary quickly. We began work on mRNA-1273 immediately after the genetic sequence of the novel coronavirus was released on January 11, 2020. Only 25 days later, on February 7, 2020, Moderna completed its first clinical batch of mRNA-1273. The Phase 1 study, led by NIH, dosed its first participant on March 16, 2020. On May 18, 2020, we announced positive interim results from the mRNA-1273 Phase 1 study, showing the generation of neutralizing antibody titer levels in all eight initial participants. In July 2020, the NIH and other authors published a fuller set of interim data and results of the Phase I study in the *New England Journal of Medicine*. Those results indicated that the vaccine produced neutralizing antibody titers in all 45 participants evaluated.

The first participants in our Phase 2 study were dosed on May 29, 2020, and we completed enrollment of all 600 subjects in our Phase 2 study on July 8, 2020. While the Phase 2 study was pending, we began our Phase 3 study in July 2020. We enrolled 30,000 participants in a randomized and placebo-controlled study, which was conducted in collaboration with NIAID. Recognizing the importance of including a representative population in this important study, we and NIAID made a concerted effort to enroll participants from communities that have historically been under-represented in clinical research and have been disproportionately impacted by COVID-19. The study ultimately included more than 11,000 participants from communities of color, representing 37% of the study population. On November 30, 2020, we announced that data from our Phase 3 clinical trial demonstrated a 94% efficacy rate against COVID-19. Efficacy was consistent across age, race and ethnicity, and gender demographics. The interim results from the Phase 3 trial were later published in the *New England Journal of Medicine* and confirmed the efficacy and safety of the vaccine. The data from our Phase 3 trial also suggest that our vaccine prevents severe cases of COVID-19, with no severe cases of the disease occurring in the trial participants who received the vaccine.

On December 18, 2020, the FDA authorized Moderna's COVID-19 vaccine for distribution under an EUA. The next day, the U.S. Centers for Disease Control and Prevention's ("CDC") Advisory Committee on Immunization Practices unanimously voted to recommend the use of Moderna's COVID-19 vaccine in people 18 years of age and older. In the days and weeks that followed, additional countries authorized the use of Moderna's vaccine. Canada authorized the use of our vaccine shortly before the end of the year, while Israel, the European Union, and the United Kingdom authorized the vaccine in the first days of 2021.

IV. Moderna Is Working with Partners to Produce and Deliver mRNA-1273

We are now focused on working closely with our manufacturing partners and the federal government to produce, fill, and deliver vaccine doses rapidly, with robust commitment to safety and quality.

A. Overview

Producing and delivering a vial of mRNA-1273 is a multiple-stage process. The first stage is to create large batches of the drug substance: mRNA encapsulated in a lipid nanoparticle. For the U.S. supply line, this stage takes place in two places: Moderna's manufacturing facility in Norwood, Massachusetts, and a facility in Portsmouth, New Hampshire operated by our contract manufacturing partner, Lonza Ltd. ("Lonza"). The use of such partners is common in the biopharmaceutical industry, and Lonza is one of the world's leading contract manufacturers. This first stage is itself a multistep process that requires the availability of raw materials and consumable supplies, such as the custom-made plastic bags that line the tanks in which the drug substance is made.

The second major stage of the production process is filling vials with the drug substance. As is common in the industry, we have partnered with a contractor, Catalent, Inc. ("Catalent"), that specializes in this "fill-finish" process. Catalent is filling vials with our vaccine at its biologics facility in Bloomington, Indiana. We are in the process of onboarding another fill-finish partner with a U.S. facility to expand our capacity at this stage of the process. As with the first stage, putting mRNA-1273 into vials is itself a multistep process that depends on the availability of supplies.

The third major stage of the production process is inspecting, testing, and packaging the filled vials for delivery. Catalent also manages this multistep stage, and our capacity will be supplemented when we fully onboard an additional fill-finish partner.

On any given day, millions of doses of mRNA-1273 will be at different stages of this process. Over time, the buildup of the product and other necessary supplies generally allows subsequent stages to operate more efficiently. The pace of production also increases as the process gets refined and the highly skilled and experienced personnel operating that process gain greater familiarity with it.

Throughout this process, Moderna and its partners are committed to maintaining the highest standards of safety and quality. That commitment requires careful planning and specialized learning; it can also extend the production timeline. It is essential, however, to maintain public confidence in biopharmaceutical products like our vaccine.

B. Production Update

Moderna and its partners began to raise additional investor capital to modify and expand our manufacturing and distribution chains for mRNA-1273 well before the FDA authorized the vaccine for use in the United States. Those efforts were complimented by additional funding from BARDA, which also facilitated our agreements to collaborate with Lonza in May 2020 and

with Catalent in June 2020. Working with those partners, we began to scale up the production process and manufacture doses for potential distribution under our supply agreement with the U.S. government.

We began delivery to the federal government promptly after the FDA issued its EUA. By the end of December, we had delivered 17.8 million doses to the federal government. To date, Moderna has delivered over 45 million doses of our vaccine to the federal government. Tens of millions of doses are at different stages of the production process. We are on track to meet our original commitment of delivering the first 100 million doses to the federal government by the end of March.

Less than two weeks ago, we reached an agreement with the federal government to accelerate the delivery of the second hundred million doses and to deliver a third hundred million doses on an advanced schedule. We are now planning to deliver the second hundred million doses by the end of May, rather than the end of June. We plan to complete delivery of the third hundred million doses by the end of July, moved up from the end of September. We plan to ship doses as they are released. We are able to accelerate these delivery timelines—while maintaining a robust commitment to safety and quality—thanks to the highly-skilled and experienced workers at our Massachusetts facility, our raw material suppliers, our contract manufacturing partner Lonza, and our fill-finish contractor Catalent. Allocation for the VA system is administered by the federal government, and Moderna is ready to assist in any way it can to improve distribution to our military veterans.

Since the end of 2020, we have doubled our monthly deliveries to the U.S. government, and we are working to double them again by April to more than 40 million doses per month. As we work to meet these goals, we are continually learning and working closely with our partners and the federal government to identify ways to address bottlenecks and accelerate our production. For example, one of the recently identified constraints on our production process has been the capacity of the fill-finish process. To reduce this constraint, we studied the possibility of adding more doses to each vial of vaccine. Doing so would improve output because it allows us to complete manufacturing runs more quickly; it also reduces the need for consumable materials in high demand. The FDA has given us positive feedback on our proposal, and we are pursuing a plan that may allow up to 15 doses to be drawn from each vial. This will allow us to produce and deliver more doses more quickly. We will continue to collaborate with our manufacturing partners and the federal government to increase the efficiency of our production process without compromising quality or safety.

* * * * *

During this period, Moderna is continuing research and development efforts to address the COVID-19 pandemic. For example, we are closely monitoring emerging variants and testing the performance of our vaccine against them. We are also studying potential booster shots, either of the existing vaccine or of a version that has been adjusted to address significant variants. We are also conducting a trial of the safety and efficacy of our vaccine in younger populations, with the hope of being authorized to provide our vaccine to adolescents aged 12 to 18 by the fall.

This pandemic remains a challenge unlike anything that we have faced in recent memory. At Moderna, we are grateful for the opportunities we have had to collaborate with the government on our efforts to deliver a safe COVID-19 vaccine. We are also grateful for the many companies around the world that are working to deliver COVID-19 vaccines and treatments.

Finally, we would like to thank this Committee for its commitment to this cause. We deeply appreciate the actions you and your colleagues in Congress have taken to support and fund efforts to combat this pandemic, and we remain committed to collaborating with the U.S. government in this fight.

Pfizer's Written Testimony for Senate Veterans' Affairs Committee
February 24, 2021
Vaccines for Vets: Our Best Shot at Ending the COVID-19 Pandemic

Introduction

Chairman Tester, Ranking Member Moran and Members of the Committee, thank you for inviting us to provide written testimony. Pfizer is thankful to all veterans for their patriotism, their selflessness and their sacrifice. And, we are proud to call many men and women who have served in the armed forces Pfizer colleagues.

At Pfizer, our purpose is: Breakthroughs that change patients' lives. In the face of COVID-19, we recognize that this need is more urgent than ever, and we have harnessed the full breadth and depth of our colleagues and their expertise from across our organization to help address this global pandemic. We know that safe and effective vaccines are pivotal to defeating this pandemic and providing protection from the threat of infection. We are committed to bringing our deep heritage and experience in vaccine development, which spans more than 130 years, our reach and scale, and our financial capital to serve the billions of people around the world impacted by this devastating illness and its consequences for their lives and livelihoods.

We, along with our collaboration partner, BioNTech, have moved at the speed of science to develop, manufacture and distribute the Pfizer-BioNTech COVID-19 vaccine. Our pace has been set by patient safety and the deadly public health emergency we face. We have made an unwavering commitment to ensure that our vaccine was proven to be both safe and effective before it was made available to the general public.

Authorization of Pfizer's COVID-19 Vaccine

On December 11, 2020 – just 269 days after announcing our initial plans to partner with BioNTech to bring forward a potential COVID-19 vaccine – our COVID-19 vaccine became the first to be granted emergency use authorization by the FDA. Two days later the first trucks started rolling out of our Kalamazoo, Michigan plant to begin delivering millions of doses of vaccine to the American people.

The FDA based its decision on the totality of scientific evidence shared by the companies, including data from a pivotal Phase 3 clinical study and published in The New England Journal of Medicine. The Phase 3 data demonstrated a vaccine efficacy rate of 95% in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The Data Monitoring Committee for the study has not reported any serious safety concerns related to the vaccine. Efficacy was consistent across age, gender, race and ethnicity demographics. All trial

participants will continue to be monitored to assess long-term protection and safety for an additional two years after their second dose.

Thus far, millions of people have been vaccinated with the Pfizer-BioNTech COVID-19 vaccine. No serious safety concerns have been identified that have changed the favorable risk-benefit profile of the vaccine.

Manufacturing and Supply

Pfizer operates one of the most sophisticated supply chain systems in the industry with over 40 Pfizer-owned global sites and employs approximately 10,000 U.S.-based manufacturing colleagues.

mRNA vaccines are an extremely innovative new technology that required the rapid development and scale-up of novel manufacturing technologies. In order for Pfizer to manufacture our COVID-19 vaccine, we had to design and develop a brand-new manufacturing process that never existed before to produce this brand-new vaccine technology – and we did it within a year – to great success.

As of February 17, we have shipped approximately 95 million doses of our COVID-19 vaccine worldwide, of which approximately 40 million doses have been shipped to points of use as directed by the U.S. Government (USG).

As this pandemic continues, we know that there is a dire need to vaccinate more people. So, we have explored innovative plans to increase the number of doses we are able to produce globally by the end of 2021. As a result of these efforts, we recently raised our forecast of manufacturing 1.3 billion doses worldwide to at least 2 billion doses worldwide by the end of 2021.

This is possible because of our significant investments in many of our U.S. manufacturing sites including Saint Louis, MO, which is responsible for raw material manufacturing; Andover, MA which focuses on drug substance; Kalamazoo, MI and Pleasant Prairie, WI for distribution.

Further improvements have come from FDA's recent approval of a 6-dose label for each vial, continuous process improvements to our existing production lines – in essence more doses from the current lines; expanding the supply of raw material from existing suppliers and bringing on new suppliers. Also:

- We have doubled our batch sizes in order to minimize time between batches and increased the yield per batch – we know that every dose counts;
- We are reducing cycle times at every step and deploying faster laboratory test methods to reduce release times;
- We have also added new fill/finish lines at our site in McPherson, Kansas; and
- We have added lipid production at our site in Groton, CT.

This is the fastest and largest capacity expansion in Pfizer's history.

Distribution

Pfizer has developed detailed logistical plans and tools to support effective vaccine transport, storage and continuous temperature monitoring. Our distribution is built on a flexible, just-in-time system to

ship the vaccine from our manufacturing site or storage facility directly to the points of vaccination. In the U.S., we have a 99.9% shipment success rate.

We also have developed packaging and storage innovations to be fit for purpose for the range of locations where vaccinations are taking place. We have specially designed, temperature-controlled thermal shippers utilizing dry ice to maintain recommended storage temperature conditions. Over the past several months, we have worked closely with state and local officials, as well as health care providers, to provide guidance on our storage requirements to help ensure our vaccine can reach people in rural and other harder to reach communities across the U.S.

In addition to our three current storage options at points of use, we submitted new data to the U.S. Food and Drug Administration demonstrating the stability of our COVID-19 vaccine when stored at -25°C to -15°C (-13°F to 5°F), temperatures more commonly found in pharmaceutical freezers and refrigerators. This proposed update would allow for vaccine vials to be stored at these temperatures for a total of two weeks as an alternative or complement to storage in an ultra-low temperature freezer.

We are utilizing GPS-enabled thermal sensors in every thermal shipper with a control tower that will track the location and temperature of each vaccine shipment across their pre-set routes.

While a great deal of attention has been focused on cold chain distribution of mRNA vaccines, we are proud of the innovations we have brought forward to address these challenges, specifically the development of detailed logistical plans and tools to support effective vaccine transport, storage and continuous temperature monitoring.

Working with the U.S. Government

Pfizer is working with the USG to help deliver the vaccine to Americans as quickly as possible. Pfizer is engaged with the representatives within various agencies within the U.S. Government regarding manufacturing or distribution of the vaccine.

At this time, our EUA permits us to supply COVID-19 vaccine to the USG; we provide the USG a rolling forecast of vaccine doses available for shipment each week that enables the USG to provide states with three weeks of data. The federal government allocates those doses, which is their purview. The federal government has a resource on total doses administered as reported to the CDC, including data on Veterans Health, at covid.cdc.gov.

On February 12, 2021, we announced that the USG exercised its option for an additional 100 million doses of the Pfizer-BioNTech COVID-19 vaccine, bringing our current total U.S. supply commitment to 300 million doses, enabling the vaccination of up to 150 million Americans.

We continue to work closely with the USG on our production, release and shipping schedules to help states ensure Americans receive their first and second doses of the vaccine on time. Our current estimates for the 300 million contracted doses to be made available to the USG for shipment are:

- 120 million doses by the end of March;
- the next 80 million doses by the end of May, which is earlier than originally planned; and
- the remaining 100 million doses by the end of July.

While we are proud of these increases, we share the concern of Congress and the Administration about equitable access to COVID-19 vaccines, and we support a robust national campaign to help build confidence in COVID-19 vaccines with particular focus on African American, Latinx, Native American, and other communities that have faced the most serious health consequences from the pandemic.

Closing

None of this could have been possible without the more than 46,000 courageous and diverse participants who volunteered to be a part of this trial, the majority of which were in the U.S.; and the thousands of Pfizer and BioNTech scientists, clinicians and manufacturing professionals who have worked tirelessly in many cases day and night, knowing that every moment matters.

It is both a great privilege and responsibility for all Pfizer colleagues and we are focused every day knowing we are all working towards a common objective — to defeat this virus. We will be fighting every step of the way until this devastating pandemic is under control.

Johnson & Johnson

Statement of

Dr. Richard Nettles, M.D.
Vice President of U.S. Medical Affairs, Janssen Infectious Diseases and Vaccines
Johnson & Johnson

before the

Committee on Veterans' Affairs
U.S. Senate

February 24, 2021

Chairman Tester, Ranking Member Moran, and Members of the Committee, thank you for the opportunity to discuss Johnson & Johnson's efforts to develop, produce, and distribute a vaccine to protect against the virus that causes COVID-19. I am pleased to have the opportunity to update you today on the remarkable progress that we have achieved over the past several months, which has allowed us to request emergency use authorization (EUA) from the Food and Drug Administration (FDA) less than three weeks ago. Although we are cautious not to prejudge the outcome of the ongoing FDA review process, we believe that our single-dose COVID-19 vaccine will be a critical tool for fighting this global pandemic. Mr. Chairman, we look forward to working with this committee and the Department of Veterans Affairs.

Johnson & Johnson is the world's largest and most broadly based healthcare company. We are committed to using the full breadth of our expertise and experience to improving health outcomes around the world. A century ago, Johnson & Johnson played a leading role in combatting the 1918 flu pandemic, and our history of confronting global healthcare challenges continues to the present day, including with the European approval of our Ebola vaccine last year.

We brought this same approach to the COVID-19 pandemic when, in January 2020, we launched a major research and development effort for a vaccine. The pace of development over the past year was extraordinary. We conducted an intensive evaluation of vaccine candidates, culminating in the selection of a candidate for a single-dose regimen. We began initial human clinical trials in July, launched our large-scale pivotal clinical trial in September, released topline interim results last month, and sought an EUA on February 4.

Even with this accelerated timeline, Johnson & Johnson adhered to our principles of putting patients first by committing to high-quality Phase 3 studies, taking extra steps for safety oversight, seeking diverse populations for our clinical trials, and performing rigorous scientific examinations of the trial data. As an infectious disease physician, I have decades of experience fighting challenging diseases around the globe. Johnson & Johnson's work to date, along with others in the industry, has been remarkable. I am pleased to provide an update on our efforts.

Trials, Results, and FDA Application

In July 2020, we began a Phase 1/2a first-in-human clinical trial in healthy volunteers in the United States and Belgium. We also launched a Phase 1 study in Japan, and a Phase 2a study in the Netherlands, Spain, and Germany. Interim results from the Phase 1/2a trials demonstrated the safety profile and immunogenicity of the vaccine after a single dose.

In September 2020, Johnson & Johnson launched ENSEMBLE, a large-scale, randomized, Phase 3 clinical study. We used sophisticated predictive models to recruit diverse participants, including from sites where new variants of COVID-19 have emerged. Ultimately, the trial included nearly 45,000 participants from eight countries across three continents, including a diverse and broad population in the United States, Central and South America, and South Africa. In January 2021, we announced that our single-dose vaccine met the study's primary and key secondary endpoints.

The study showed that our single-dose vaccine addresses the most important healthcare need in the pandemic: the prevention of COVID-19 related hospitalization and death. Importantly, this result was achieved across emerging variants, including the virulent B.1.351 variant first observed in South Africa, and the P2 variant first observed in Brazil. Specifically, the study showed the following outcomes, twenty-eight days after vaccination:

- The vaccine provided complete protection against COVID-19 related hospitalization and death, as compared to those study participants who received a placebo.
- The vaccine demonstrated 85% effectiveness overall in preventing severe disease, including across countries with newly emerging variants.
- The vaccine demonstrated 72% effectiveness in the United States (and 66% effectiveness overall) at preventing moderate to severe disease.

Based on these clinical trial data, Johnson & Johnson earlier this month submitted an application to the FDA for emergency use authorization for the vaccine. The FDA subsequently announced that the agency's Vaccines and Related Biological Products Advisory Committee will meet to review the vaccine this week, on Friday, February 26. We are working with the FDA to ensure that the agency has the information necessary to reach a decision based on the data relating to the safety, efficacy, and quality of the vaccine.

Production and Distribution

We are working around the clock to develop and broadly scale our manufacturing capabilities to supply the United States, and we are appreciative of the ongoing and extensive collaboration and partnership with the U.S. government. Assuming necessary regulatory approvals relating to our manufacturing processes, our plan is to begin shipping immediately upon emergency use authorization, and deliver enough single-doses by the end of March to enable the vaccination of more than 20 million Americans. We are confident in our plans to deliver 100 million single-dose vaccines to the United States during the first half of 2021, and we are continuing to partner with the U.S. government to explore all options to accelerate delivery.

We are working with urgency, in collaboration with the government and others, to continue to increase production significantly throughout the year. To that end, we have been working to expand our own manufacturing capacity and to contract with established third-party vaccine manufacturers for additional production. Our current manufacturing plans are designed to meet our objective, which we announced last year, to produce the vaccine at a rate of one billion doses globally by the end of 2021.

Throughout the pandemic, Johnson & Johnson has focused on building a global supply network in parallel with the research and development of our vaccine. We began preparing for clinical vaccine production in our facility in the Netherlands in July 2020. Since then, we have increased manufacturing capacity significantly and continue to activate new manufacturing sites as quickly as possible, subject to approvals by the relevant health authorities. Our goal is to have seven COVID-19 vaccine manufacturing sites active by midyear. We have entered into agreements to expand our manufacturing capability, including by collaborating with established manufacturers in the industry, and we continue to pursue opportunities to expand our manufacturing capabilities with additional production sources.

The production of our vaccine is a highly complex process that requires very particular capabilities and experiences. As a result, there are significant challenges inherent in scaling manufacturing output and accelerating the timeline needed for a COVID-19 vaccine.

Over the past several months, we assessed nearly 100 different potential production sites, and we selected eight sites that were able to support an accelerated timeline. Three sites have produced process performance qualification batches of the vaccine, and we expect additional capacity to become available in the second quarter of 2021.

The production of the vaccine generally consists of two separate processes – the manufacturing of the drug substance and the manufacturing of the drug product. Attached to my testimony is a fact sheet on our vaccine production and distribution process.

The production of the drug substance takes about two months, due to the time necessary to grow the required biological cells and then purify the active vaccine. Our current plans call for the production of drug substance at sites in the United States, Europe, and Asia. The site in the United States is in Maryland. Production will occur both on existing production equipment and on new specialized equipment being activated for our vaccine.

The manufacturing of the drug product takes about five to six weeks to produce, test, and release. The necessary production timeline is also driven by the time required for cellular growth and sterility. Our plan is to manufacture drug product at sites in the United States, Europe, Asia, and Africa. In the United States, the drug product production sites are in Indiana, Michigan, and Pennsylvania. As with the drug substance, the production of the drug product will occur both on existing production equipment and new specialized equipment. Regulatory inspections and approvals for these sites are ongoing.

In the event that the FDA grants our request for an emergency use authorization, we have doses ready to ship immediately upon authorization. In the United States, Johnson & Johnson will distribute our vaccine through an agreement with the U.S. government for the production of

100 million vaccine doses. Pursuant to our agreement with the government, Johnson & Johnson will deliver the vaccine to a distributor that will create a vaccination kit containing our vaccine and the necessary ancillary equipment, such as syringes and personal protective equipment.

In addition to our commitment to provide millions of vaccine doses in the United States, Johnson & Johnson recognizes the global nature of the pandemic and the need for broad access to COVID-19 vaccines. We have therefore pledged to provide vaccine doses to lower income countries beginning this year. We committed to provide vaccine doses to COVAX, the initiative led by the Global Alliance for Vaccines and Immunization, the World Health Organization, and others, to provide equitable access to COVID-19 vaccines.

Importantly, the characteristics of our vaccine permit it to be distributed using the existing cold supply chains that we use to transport other medicines today. We estimate that the vaccine will remain stable for up to two years at -20° Celsius, and at least three months at routine refrigeration temperatures between 2° and 8° Celsius. Because the vaccine is compatible with standard vaccine distribution channels, it does not require new infrastructure for its distribution. We believe our current distribution channels include enough temperature-controlled trucks, containers, and planes to deliver the vaccine as needed. In addition, each vaccine pallet will include tracking technologies that will give us real-time location, temperature, and other information needed to maintain the quality and integrity of the vaccine.

Vaccine Technology

Johnson & Johnson's AdVac technology is the foundation of our COVID-19 vaccine. We have employed the same AdVac technology to develop our Ebola vaccine, which received European Commission approval last year, and to construct our vaccine candidates for HIV, respiratory syncytial virus, and Zika. We have significant clinical experience with vaccines based on the AdVac technology. Vaccines based on this technology have been administered for more than a decade to a wide variety of populations, such as adults, people over age 65, infants, children, and pregnant women.

To develop the COVID-19 vaccine, we combine DNA that codes for the coronavirus spike protein and the AdVac technology that uses a nonreplicating adenovirus as a carrier. The resulting combination mimics components of the COVID-19 pathogen and triggers the immune system while not leading to infection. When the body encounters this antigen, it produces antibodies and T cells. If the body later encounters the actual COVID-19 pathogen, the body will be able to respond faster and more effectively, as immune cells and antibodies specific to the pathogen are produced rapidly in the body to prevent the pathogen from inducing disease.

Vaccine Safety, Transparency, and Diverse Populations

In September 2020, Johnson & Johnson joined with eight other companies working on COVID-19 vaccines to reiterate our commitment to develop and test potential vaccines in accordance with high ethical standards and sound scientific principles regarding the conduct of clinical trials and the rigor of manufacturing processes. The companies pledged to make the safety and well-being of vaccinated individuals the top priority, as well as to work to ensure a sufficient supply and range of vaccine options, including those suitable for global access. The

companies also pledged to submit the vaccines for regulatory approval or emergency use authorization only after demonstrating safety and efficacy through a Phase 3 clinical study consistent with the requirements of expert regulatory authorities.

For Johnson & Johnson's Phase 3 COVID-19 vaccine studies, we established independent expert vaccine Safety Advisory Boards to consult and advise on safety risk management. In addition, independent Data and Safety Monitoring Boards oversee the safety of the entire clinical program. These measures are in addition to our standard oversight of safety during the course of our studies.

Johnson & Johnson is committed to disclosing the trial data on external public registries, such as ClinicalTrials.gov and the EU Clinical Trials Register. We expeditiously seek publication of all results from clinical trials in patients in peer-reviewed medical journals and will do the same for our vaccine trials. To that end, our preclinical studies were published in scientific papers, and our Phase 1/2a study data were published in the New England Journal of Medicine. For our Phase 3 COVID-19 vaccine studies, the Clinical Study Reports and clinical trial participant data will be made available for sharing through the Yale University Open Data Access Project after regulatory approval.

Johnson & Johnson has led efforts to ensure that clinical trials include a wide variety of populations, including historically underrepresented communities. In our COVID-19 vaccine trials, we employed an engagement strategy to reach underserved and underrepresented communities. The ENSEMBLE study of 45,000 participants included diverse and broad populations. Among the participants worldwide, 45% were Hispanic or Latinx, 19% were Black or African American, 9% were Native American, and 3% were Asian. More than one-third of participants were over age 60. For participants in the United States, 15% were Hispanic or Latinx, 13% were Black or African American, 6% were Asian, and 1% were Native American.

Thank you for the opportunity to provide this update regarding our efforts to develop, produce, and distribute a vaccine against COVID-19. Again, we look forward to working with the Committee to answer any questions you may have regarding our single-dose COVID-19 vaccine.

Johnson & Johnson

Janssen Supply Chain

COVID-19 Vaccine Manufacturing

At Johnson & Johnson (J&J), we take seriously our responsibility to supply our COVID-19 vaccine candidate around the world upon approval, and are confident we have the capabilities, collaborations, and rigorous safety and quality standards to do so.

Vaccine Production and Distribution Process

1
In the production process, **cells are grown** and replicated in a controlled environment to generate "drug substance."

Quality control: Collect samples and perform testing.

2
The drug substance is **frozen at -60 °C** in bottles to preserve stability before drug product manufacturing.

3
Those bottles are **transported at -70 °C to production/ fill-finish sites,** often in a different country.

4
The drug substance is **thawed and diluted** into the vaccine formulation.

5
The vials are then **filled and finished with labels, then packaged.**

6
Those vials are frozen at -20 °C, and **shipped to J&J warehouses** for storage and distribution.

7
Following regulatory authorization, J&J will ship the vaccine for distribution using the **same cold chain technologies** we use today to transport other innovative medicines.

With Janssen's AdVac® technology platform, the vaccine is **estimated to remain stable for two years at -20 °C (-4 °F)**, three months of which can be at temperatures of 2-8 °C (36-46 °F).

Each pallet of our vaccine will include **track-and-trace technologies** that will provide real-time location, temperature and other information needed to maintain the vaccine's quality.

The general timeframe to produce a batch of vaccine, from drug substance to fill and finish, is **60–70 days, plus 18–22 days** for final product quality testing and release.

Global Manufacturing Collaborations

Given the unprecedented nature of the pandemic, Johnson & Johnson is expanding its global manufacturing capacity. We have established new U.S. vaccine manufacturing capabilities and are scaling up capacity in other countries.

In addition to our existing manufacturing capacity in Leiden, the Netherlands, we have entered into multiple agreements to expand our manufacturing capability of our COVID-19 vaccine candidate.

Manufacturing Partners

Drug substance · Drug product · Fill-finish

Due to the global interconnectivity of our production and supply chain processes, one batch of the J&J COVID-19 vaccine **will likely visit multiple countries** through the course of various manufacturing stages in its journey from drug substance to a finished vial for injection.

For more information on Johnson & Johnson's approach to help combat COVID-19, **visit www.jnj.com/coronavirus.**

© Johnson & Johnson
Last updated: January 2021

Department of Veterans Affairs (VA)
Questions for the Record
Committee on Veterans' Affairs
United States Senate
Oversight Hearing

February 24, 2021

Questions for the Record from Ranking Member Moran

Question 1. **Dr. Stone, it seems other Veterans Integrated Service Networks (VISNs) and VA medical centers (VAMCs) are struggling to properly distribute vaccines to our Veterans in rural and highly rural areas. In an article that appeared in *Military Times* on February 20 titled, "For VA, where Veterans live is a bigger factor in COVID-19 vaccine refusal than race," you shared that there is vaccine reluctance or outright refusal from many rural Veterans. You were quoted, "In one area of New York alone, over 1,000 Veterans over age 75 said 'no thank you.' And that surprised us." However, the data VA is sharing publicly and with this Committee doesn't quite support that conclusion.**
Can you send this internal data to my staff that illustrates VA is seeing a trend in rural Veterans refusing the vaccine?

VA Response. Utilizing data from the Office of Health Equity on COVID-19 vaccination refusal, it is noted that the vaccination refusal rate is 2.5% overall. It was noted to be 2.3% in Veterans in urban areas, 3.0% in rural areas and 3.5% in highly rural areas (March 16, 2021).

Total Vaccinations	Total Vaccination Rate	Urban Vaccination Rate	Rural Vaccination Rate	Highly Rural Vaccination Rate	Total Refusals	Total Refusal Rate	Urban Refusal Rate	Rural Refusal Rate	Highly Rural Refusal Rate
1,601,709	29%	31%	24%	23%	141,331	2.5%	2.3%	3.0%	3.5%

Question 1a. **If VA data in fact supports that there is vaccine reluctance among rural Veterans, what plans can the Department share with me and this Committee on how the VA can stem-the-tide on this issue?**

VA Response. The goal is to provide COVID-19 vaccine at locations convenient to rural Veterans and with less drive time than the local VA facility. Expanding the reach of COVID-19 vaccination will provide access to vaccines for rural Veterans for whom drive time distance is a reason for refusal. VA and the Centers for Disease Control and Prevention (CDC) have been working on communications products to address vaccine hesitancy, or vaccine non-acceptance.

VA's strategic communications approach to addressing vaccine hesitancy began at the grassroots level. VA conducted Veteran listening sessions and is collaborating with outreach offices that serve varied stakeholder-focused audiences, including minority, women, tribal and rural Veterans, to develop COVID-19 vaccine messaging that will

motivate these audiences. VA experts indicated that the most effective way to help hesitant Veterans and employees feel more confident in getting the vaccine was to ensure they hear recommendations from their local doctor or community leaders. VA health providers have been encouraging vaccine acceptance with Veterans during clinical appointments.

VA has developed materials to encourage vaccine acceptance, including fact sheets addressing COVID-19 vaccine myths, social media content and change management products to help alleviate concerns about COVID-19 vaccines. These products are available in the COVID-19 Vaccine Communication Toolkit, which are accessed for use by Public Affairs Officers (PAOs), leadership and other VA employees. Strategies for using these products are shared with PAOs on weekly calls as well.

Question 2. **Dr. Stone, also regarding rural vaccine distribution, I'm aware of a pilot program the Department is deploying in Montana and Oregon where vaccines are flown in by a privately chartered plane. Has this pilot program been successful thus far and what are the VA's detailed plans for expanding to other rural states?**

VA Response. These pilot programs were successful as is indicated by these two links:

- https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5610
- https://blogs.va.gov/VAntage/84499/veterans-rural-montana-receive-covid-19-vaccine-via-airplane-delivery/

It is important to note that not all outreach to rural areas will or should look the same. For example, in New Mexico, there has been highly successful outreach to rural and outlying clinics by ground transportation and it was noted that use of a fixed wing plane would not be practical given the terrain. Sites across VA are working to determine the best way to reach rural Veterans based on the needs, local conditions and resources available.

Question 3. **Dr. Stone, in your written testimony you provided an insight to VA's allocation process to VISNs that is similar to how the Department of Health and Human Services (HHS) allocates vaccine to the states. Are the VISN's bound to this pro-rata allocation formula when re-allocating to its network of facilities? If so, is this VA Central Office (VACO) policy or is it a voluntary approach that the VISNs are free to use or disregard?**

VA Response. Allocation for each VISN is determined centrally. Currently, VA provides distributions to VISNs based on their proportion of enrolled Veterans who are 65+, because 65+ Veterans make up the majority of CDC Phase 1b and Phase 1c as many of our facilities have worked through most of Phase 1a (health care personnel and Veteran long-term care facility residents). VISN leadership determines how the vaccine is allocated and redistributed across the VISN within the allotted allocation. VISNs can

distribute vaccine outside of the pro-rata formula to facility sites, including CBOCs, based on demand signals such as scheduled appointments for vaccinations and planned mass vaccination events.

Question 4. **Dr. Stone, last week my staff was informed that VA's Risk Stratification Framework includes vaccinating Veterans based on occupation starting in Phase 1B with frontline workers and essential workers. They were told that all the VISNs are aware of this and are vaccinating Veterans based on occupations. However, my staff have heard differently on the ground. Can you clarify whether it is VACO guidance for VISNs and facilities to vaccinate Veterans based on occupation?**

VA Response. The guidance from VACO includes front line essential workers as defined by CDC in Phase 1b. Phase 1b also includes Veterans who are 75 and older and specific high-risk populations of Veterans. Overall, this constitutes a large group of the patients we care for. As VA is a health care system, we have ready access to information on health conditions and age, but information on current employment sector may be incomplete. All facilities are aware of the risk stratification guidance but have flexibility to implement vaccination in a way that balances local needs and resources.

Question 4a. **If it is VACO's policy, can you detail how you are ensuring the policy is being followed by facilities?**

VA Response. It is not policy. VACO has issued guidance on best practice, based on the Advisory Committee on Immunization Practices (ACIP) and CDC recommendations. Given the emergence of variant strains of COVID-19 and the quick turnaround between ordering and arrival of vaccine, any local vaccination plan also must consider feasibility and maximize efficiency. ACIP and CDC similarly recognize the challenges in reliably identifying persons working in the essential workforce, outside of self-report or organization on the part of their employer. While we ask that sites ensure Veterans reporting work in front line essential occupational groups as defined by CDC have access to vaccine (subject to availability/supply) during Phase 1b, this is not a group for whom the denominator is well defined.

Question 4b. **Additionally, what guidance have you given the VISNs to verify occupation status of Veterans?**

VA Response. VACO does not require sites verify employment status of Veterans self-reporting occupation in the front-line essential work force or non-front-line essential work force. This verification is based on trust in our Veteran patients and on ethical concerns that requiring such verification could present barriers to vaccination depending on how that process is implemented. Adding the step of requiring verification also could cause significant issues with efficiency of the vaccination effort across VA. While some sectors in the essential workforce may easily provide identification, other sectors, for example, agriculture or construction, may face difficulty. Again, efficient vaccination is

critical in protecting individuals and in stopping the spread of COVID-19 in the United States and sites have flexibility on implementation.

Question 5. **Dr. Stone, from my understanding, VACO developed communication toolkits but ultimately it is up to the VISN and facilities to decide the best means for reaching out to the Veteran. Has VACO provided the VISNs with any additional policy on how to conduct outreach efforts? Have you established a minimum number of touch points for the VISNs when attempting to schedule vaccine appointments or a minimum method of communication?**

VA Response. The Communications Toolkits are not posted just on an easily accessible SharePoint site, they are shared also with Veterans Health Administration Central Office (VHACO) communication teams during national weekly meetings where they are given guidance on the best approaches and channels on how to use the products. As issues arise, toolkits help to guide local discussions on issues such as minority hesitancy.

They are also shared on monthly calls with VISN and facility PAOs to discuss communication issues, provide updates about available products and share strategies and best practices as to how products are being used. PAOs have been particularly innovative in COVID-19 vaccine communication efforts and the open exchange of ideas across all levels of the organization.

In addition, VA vaccine leadership present daily and weekly updates to VISN and VAMC leadership, as well as program office and vaccine coordinators. These presentations include products and approaches for communications and outreach, including touchpoints such as the Annie App, VetText, letters, phone calls and the "Sign up to get a COVID-19 vaccine at VA | Veterans Affairs" website.

Question 6. **Dr. Stone, I was glad to hear that VA had developed the Veteran Outreach Tool to help VISNs determine Veteran eligibility based on the Risk Stratification Framework and create priority lists. However, I have learned that VISNs are not required to use the tool and more importantly, the tool does not capture all priority Veterans. For example, if a Veteran is enrolled in VHA but receives most of their care through other means, the tool will not capture that Veteran even if that Veteran has a 100% disability rating or is high-risk. What is VA doing to address this gap? Are you incorporating VBA data into the algorithm to help address this issue?**

VA Response. VHA recognizes all data is subject to error and efficiency of vaccination is critical during the COVID-19 pandemic. The greatest magnitude of risk from COVID-19 relates to increasing age and we are confident in VA data regarding this. We are using the data we have on additional risk factors, which is robust. The Veterans Outreach tool facilitates invitation of those Veterans with known risk factors for vaccination. In addition, Veterans may choose to identify high-risk conditions they have

not reported previously to their VA care team by calling their patient-aligned care team (PACT).

Question 7. **Dr. Stone, is it true that the remaining $10.5 Billion in CARES funding will meet COVID-specific needs such as personal protective equipment (PPE), testing, equipment, supplies and increased health care costs through most of the remainder of this fiscal year?**

VA Response. Yes, VHA has a spend plan and will be using CARES funding to meet COVID-specific needs throughout the remainder of FY 2021.

Question 8. **Dr. Stone, is it true that the $17 Billion in the American Rescue Plan (ARP) for VA is targeted largely at needs that may occur in FY 2022 and beyond based on modeling of "pent up" health care demand? Are VA facilities seeing demand for health care now that exceeds what you expected for 2021 in terms of outpatient visits, inpatient visits etc.?**

VA Response. VHA is planning for the ARP funds to support Veteran-deferred health care that is being projected as Veterans present health care needs that have been delayed during the COVID-19 epidemic surge. VHA currently is scheduling health care and support critical to effectively tackle the urgent public health and economic crisis the Nation faces as a result of COVID-19. The VA funding will ensure veterans have continued access to quality health care and protections against COVID-19, as well as providing needed economic relief. Funding provided to VA will enable the Department to address COVID-related impacts and other resource needs in FY 2022.

Question 9. **Dr. Stone, given that there is $10.5 Billion left in CARES, would it not be prudent to wait a few months to reassess the needs of the system to determine whether forecasted "pent up" demand as a result of COVID-19 is materializing? Why is it fatal to wait a few months, if not for all the $17 Billion, then at least a portion of it that's not immediately needed?**

VA Response. VA is prioritizing the use of its CARES funding to meet COVID-related needs in FY 2021, allowing VA to reserve use of certain ARP funds until FY 2022. CARES Act funds will be fully obligated this year and have addressed the initial pandemic response. However, to meet the longer-term surge and sustain investment in staff and technology, we need the ARP. ARP funds will enhance VA's COVID response in FY 2022 and provide veterans with continued access to quality health care and protections against COVID-19, and will allow for continued robust investments in suicide prevention, mental health, and other key priorities.

Now is the right time for the ARP; it means we can ensure staff hired with CARES Act funds they have job security; we can continue to support telehealth investments into FY 2022 and beyond and we can make additional investments in critical process improvements, needs that were laid bare during the pandemic response.

Questions for the Record from Senator Brown

Question 1. **We know racial disparities exist in our national health care system. We see it playing out in real time during the pandemic. COVID-19 has been a "Great Revealer," highlighting inequities within our society with Black and brown people shouldering the heaviest load as the pandemic continues. VA is not immune to implicit racial, ethnic and cultural biases that affect the quality of care experienced by patients of color. We need to do more, here in this Committee, to push VA to examine patient data and assess policy changes, which could provide better health care outcomes for Black, Latinx, Native American, women and rural veterans.**

Based on information from the Ohio Department of Health, as of yesterday, we have vaccinated 5.2% of Black Ohioans, but almost 12% of White Ohioans. That discrepancy is astounding to me.

Dr. Stone, you said in October VA did a listening session with minority Veterans to address specific concerns and we know some communities have vaccine hesitation and medical mistrust, understandable given what our government has done in the name of science to Black and Native communities. And, the history of institutional racism within our health care system continues to impact health outcomes for communities of color today. Currently VA's statistics show 25% of white, 28% of Latino and 30% of Black veterans aged 75 and older are vaccinated.

How does VA plan to ensure equitable vaccination once younger Veterans are eligible? What is VA doing to ensure Black, Latinx and Native American Veterans feel safe about getting the vaccine and how will VA increase access and information to rural Veterans so they aren't left behind?

VA Response. VA continues to monitor progress and communicate with Veterans in racial and ethnic minority groups and Veterans who reside in rural areas. Our dashboards continue to indicate that our minority vaccination rates are on target.

We note that rural vaccinations are around 25% vs. about 31% among urban Veterans. We also note that vaccine refusals are higher among rural Veterans when compared to those in urban areas. We are working on expanding access for rural Veterans and it is early to know if the lower rates of vaccination and higher rates of refusal are due to hesitancy or due to factors impacting access such as availability of vaccine and convenience of timing and location of the clinic.

We anticipate greater vaccine hesitancy among younger Veterans who are at lower risk of dying from COVID infection. So far, we have not seen racial or ethnic disparities in vaccination among younger Veterans who use VA; 32% of Black Veterans and 28% of Hispanic Veterans under age 65 have been vaccinated at VA compared with 27% of White Veterans under age 65, We do see lower rates of vaccination among younger rural Veterans compared with urban Veterans.

We know that surveys around COVID-19 vaccine indicated higher likelihood of hesitancy (non-intent to be vaccinated) in both these groups and we will continue to listen and focus communications to ensure we build on the trust between our Veterans and their care teams and to keep our momentum going forward. We have materials that debunk COVID vaccine myths overall and tailored for women and minority Veterans posted on our website (https://www.va.gov/HEALTHEQUITY/). We are completing a video to further encourage Veterans to seek vaccination.

Question 2. **During the pandemic, VA limited services to limit exposure risks, but in Ohio, we have seen some facilities use lower utilization numbers to close units. That clearly limits access for rural Veterans who want to be treated at their local VAMC; and that is unacceptable.**

VA decisions about medical facility services should be transparent and include feedback from Veterans and the frontline employees who serve them. Please provide my office with the supporting documentation that was used by VISN 10 to limit services and consolidate care at the Chillicothe VAMC. (VHA 15).

VA Response. Chillicothe curtailed operation of the 10-bed acute medical unit to shift associated resources to support the COVID-19 response within the Community Living Centers and other clinical areas. All Veterans presenting at the Urgent Care in need of admission to acute medical care have been appropriately admitted to a higher level of care at either the Dayton VAMC, Cincinnati VAMC, Wright-Patterson AFB (WPAFB) medical center or a Community Medical Center. During the peak of the COVID-19 outbreak, local community facilities around Chillicothe were at or near capacity. There were concerns about COVID-19 patients decompensating, needing critical care services and having to be transported to facilities greater than 1 hour away. This concern resulted in a heavier reliance on the Dayton VAMC, Cincinnati VAMC and WPAFB medical center during this time.

The Chillicothe leadership team and clinical leaders continue to monitor bed data. Between December 8, 2020 and January 8, 2021, a total of 138 Veterans have been transferred out for acute medical services. Upon review of the acute services required by these Veterans in comparison to the inpatient services most recently available at the Chillicothe VAMC, it was determined that 49% could have been provided care internally if beds were available. 51% required a higher level of care than recently available at the Chillicothe VAMC. Twenty-four percent of the 138 transfers were to VAMCs or Department of Defense medical facilities; 76% were to community partners. The facility continues to routinely monitor the number of patients who need an acute admission and the small number would result in a low census (3-5 per day). There are readily available beds at the local community partner currently, as well as with the two south central Ohio VA facilities providing those resources.

Question 3. **Dr. Stone, in your testimony you said VA could vaccinate as many as 600,000 people a week. Now that the J&J vaccine is approved, does VA plan to use the vaccine in rural areas? How will VA ramp up daily vaccinations to ensure that all Veterans are vaccinated?**

VA Response. VA included the Janssen vaccine in vaccination for rural and hard-to-reach Veterans, with advantages including a single dose and a favorable transportation profile. On April 13, 2021, CDC and FDA recommended pausing the use of the Janssen vaccine while reviewing rare but serious clotting events in 6 of 6.85 million vaccine recipients. VA immediately paused use of this vaccine and began contacting those at highest risk and awaits further guidance from CDC following an emergency meeting of the Advisory Committee on Immunization Practices scheduled for April 23, 2021. VA has met the pace of vaccination demand from our Veterans in care and further expanded vaccination to additional Veterans, spouses and caregivers. VA is working hard to promote vaccine acceptance.

Questions for the Record from Senator Sinema

Question 1. **For Veterans experiencing homelessness, transportation to a VAMC to receive the vaccine can be particularly challenging. In Arizona, the Phoenix VAMC did onsite vaccination with U.S Vets to overcome some of these challenges. How is VA learning from these local efforts and expanding them nationally?**

VA Response. VA continues to share best practices from individual sites on vaccine coordinator calls and has discussed utilizing offsite clinics, such as Mobile Vet Centers, to reach populations that may have difficulty traveling to a VAMC. The authorization of the Janssen vaccine in March 2021 expanded options for transportation of vaccine given increased stability for transport when compared to the Pfizer-BioNTech and Moderna vaccines.

From late February through the end of March, VA facilities have planned over 350 vaccine community outreach events, utilizing VA clinics, Veterans Service Organizations (VSO) and other community facilities. Nearly a third are dedicated specifically to rural communities, with another 138 identified as reaching a mix of rural and urban populations. The Blythe Clinic in Riverside County, California, reached over 40 Veterans by partnering with the local VSO and utilizing VetText and social media to advertise walk-in availability. In Missouri, Poplar Bluff VAMC partnered with the National Guard Armory in Butler County to administer over 240 vaccinations.

Question 2. **It is my understanding that VA has worked to expand vaccine access to Veterans through VA's Community Care Network urgent care locations and retail pharmacies now offer COVID-19 vaccinations nationwide for eligible Veterans. When and how will this be advertised to Veterans, so they are aware of this expanded capacity?**

VA Response. VA's Office of Community Care (OCC) updated its public-facing and Veteran-facing webpages to provide guidance on obtaining COVID-19 vaccines in the community through the Community Care Network (CCN).

- A fact sheet with information for Veterans was developed and shared with field staff in VA facilities to assist Veterans in the process of finding a community provider for a Vaccine.
- OCC reached out to the provider community via the Provider Advisor newsletter in the February 2021 edition with an article on the service.
- OCC partnered with VA.gov to provide community care-related information on the VHA COVID-19 public webpage and updated the Q&As related to community care.
- The websites with the information are: COVID-19 Guidance for Community Providers - Community Care (va.gov) and COVID-19 vaccines at VA | Veterans Affairs and COVID-19 Vaccinations for Veterans in the Community - Community Care

Question 2a. **What is the process by which Veterans can take advantage of this program and when will Veterans be able to take advantage of this expanded capacity?**

VA Response. Veterans must be eligible to receive the vaccine in their locality. Once they meet local criteria, eligible Veterans can receive the COVID-19 vaccine at retail pharmacies and urgent care centers in the VA CCN. Veterans can get information here: COVID-19 Guidance for Community Providers - Community Care (va.gov).
Eligible Veterans in CCN Region1-4 are eligible now to receive the COVID-19 vaccine at a CCN participating retail pharmacy or urgent care clinic as allowed by local government distribution rules.

Question 3. **Understanding that currently this is limited to caregivers enrolled in the VA's Program of Comprehensive Assistance for Family Caregivers, VA's decision to offer COVID-19 vaccination to Veteran caregivers at the same time that the Veteran receives the vaccine is critically important. My office is seeing challenges because the VAMCs have different policies for how they offer these vaccines to caregivers. Since caregivers talk to one another, it causes a lot of confusion and frustration when one caregiver at one VAMC receives a vaccine and another caregiver at a different VAMC is refused. We had one instance in which a Veteran refused to get his vaccination because his caregiver was denied. How will the VA better standardize this policy to minimize confusion and ensure local VAMCs have the resources they need to provide COVID-19 vaccines to caregivers when their Veteran receives one?**

VA Response. While we have not heard about Family Caregivers enrolled in the Program of Comprehensive Assistance for Family Caregivers facing significant barriers

to vaccination, we encourage reaching out to Facility Caregiver Support Program Staff if a Veteran is eligible for vaccine and the Family Caregiver is not able to receive vaccine. VA stands ready to expand vaccination administration to General Caregivers enrolled in the Program of General Caregiver Support Services and caregivers of Veterans enrolled in specific Geriatrics and Extended Care Services. With the passage of the "Save Lives Act", many VAMCs are already delivering vaccines to these populations. We are most appreciative of Congress's support.

○