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HEARING ON PROTECTING SCIENTIFIC INTEGRITY IN THE COVID-19 RESPONSE

THURSDAY, MAY 14, 2020

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:03 a.m., in Room 2123, Rayburn House Office Building, Hon. Anna G. Eshoo [chairwoman of the subcommittee] presiding.

Present: Representatives Eshoo, Engel, Butterfield, Matsui, Castor, Sarbanes, Lujan, Schrader, Kennedy, Cardenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Rush, Pallone (ex officio), Burgess, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, and Walden (ex officio).

Also Present: Representative O'Halleran.

Staff Present: Billy Benjamin, Systems Administrator; Jeff Carroll, Staff Director; Aisling McDonough, Policy Coordinator; Joe Orlando, Staff Assistant; Andrew Souvall,

Director of Communications, Outreach and Member Services; Jennifer Barblan, Minority Chief Counsel, O&I; Mike Bloomquist, Minority Staff Director; Tyler Greenberg, Minority Staff Assistant; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; James Paluskiewicz, Minority Chief Counsel, Health; Tiffany Haverly Minority Communications Director; and Elizabeth Allen, Burgess Health Counsel.

Ms. <u>Eshoo.</u> The Subcommittee on Health will now come to order. Good morning colleagues. The chair now recognizes herself for 5 minutes for an opening statement.

Mr. Burgess. Parliamentary inquiry as we start this hearing?

Ms. <u>Eshoo.</u> I want to do my opening statement. I already recognized myself. I will recognize you afterward.

I never thought I would be holding, or that we would be holding a hearing under these sad circumstances, but I think it is a necessary one.

Our country is in pain. Americans are afraid, they are sick, they are hungry and jobless, and over 80,000 souls have been lost. And the government that was supposed to protect them has failed. They are heroes and they have risen, extraordinary ordinary Americans showing courage, compassion and a sense of self-sacrifice and duty beyond what could have or should have been asked of them. Regular Americans have risen when their leaders have not.

We are the greatest country on Earth. And yet, we have the most cases and the most deaths from COVID-19 of any Nation in the world. Why? First is the inept, ineffective and extremely late effort to respond to what was clear to many scientists and public health experts in January. That basic delay cost precious lives, and is continuing to cost lives. We can't have a system where the price paid is unconscionable, mothers losing daughters, daughters losing fathers because of incompetence, denial, delay, and a disorganized response.

Frankly, I am tired of those who bear the responsibility, accepting none of it, while deflecting blame on others, the previous administration, the World Health Organization, the Wuhan lab, anywhere but where the blame belongs.

Second, the United States has and remains dangerously dependent on foreign countries for our supply of critical lifesaving drugs and lifesavings equipment, masks, gloves, PPE, and ventilators. As a result, we can't treat our own people without relying on China and others to supply us. We can't outfit our first responders, our hospital workers, our nurses, our doctors. We can't care for own Nation in crisis. This surely is a national security issue.

I want to thank the gentlewoman from Indiana, Ms. Brooks, for her bipartisan work with me to address the drug supply chain issue, as well as other members, on a bipartisan basis, for their legislation on those issues as well.

Today, we are going to hear about the disastrous Federal response to an approaching pandemic. Dr. Bright has filed one of the most specific and troubling whistleblower complaints I have ever seen. He was the right person, with the right judgment, at the right time. He was not only ignored, he was fired for being right. We can't have a system where the government fires those who get it right and reward those who get it completely wrong.

Mr. Michael Bowen, the executive vice president of Prestige Ameritech, will speak to America's crippling dependence on foreign countries for critical medical supplies. A public health issue, and a national security issue.

Our country is paying a terrible price today and it rests on Congress to address these threat where any effort of an adversary can cut off our supply of lifesaving drugs and supplies, our lifeline. And this would create a healthcare disaster on a scale never experienced before. I bear this responsibility, as does every Member of Congress.

This subcommittee has jurisdiction over our country's most prestigious healthcare institutions, FDA, NIH, CDC, and BARDA. We have to listen, we have to learn, and we

must work together for the people of our country who need us so, so much, regardless of inconvenient truths.

Finally, I regret that Secretary Azar, Dr. Robert Kadlec and Dr. Peter Navarro have all refused to testify today.

I now ask for a moment of silence in honor of the over 80,000 Americans who have lost their lives from COVID-19.

The chair now recognizes --

Mr. <u>Burgess.</u> Before I am recognized for an opening statement. I wonder if I might be recognized for a parliamentary inquiry.

Ms. Eshoo. The gentleman is recognized to state his parliamentary inquiry.

Mr. <u>Burgess.</u> The inquiry is I would like clarification on the witness before us today. Is this witness testifying as a government witness or as an individual?

Ms. <u>Eshoo.</u> Dr. Bright is testifying as a Federal employee, correct? And representing — he is a Federal employee representing himself.

I now recognize the ranking member of the subcommittee.

Mr. <u>Walden.</u> Madam chair, just a question. Normally we have nameplates identifying who is at the table. I know Dr. Bright, but I am not sure who is next to him.

Ms. <u>Eshoo.</u> You are correct. I don't know why we don't have nameplates. I didn't notice that when I came into the hearing room. Can the staff provide them? Is there any way the staff can provide them? I think we can.

I also would like to inform the members that Dr. Bright's attorney, Debra Katz, is at the table, she has requested a microphone. She is not here as a witness, so we will not be asking her questions. She is simply here to -- representing her client.

I now would like to recognize the ranking member of the subcommittee, Dr.

Burgess, for his 5 minutes for an opening statement.

Mr. <u>Burgess.</u> I thank the chair. And the Energy and Commerce, particularly the subcommittee on Health, is the premiere health subcommittee in the Congress. We have a broad jurisdiction, a longstanding tradition of tackling important healthcare issues in a bipartisan manner. I personally, like our witness today, have been very, very concerned, in fact, sounding the alarm about this novel coronavirus since January. So I ask, why is this the first official hearing that we are having on this topic? To say this is a disappointment would be an understatement.

But not only disappointment, but, quite frankly, I am concerned it took 5 months to have a hearing on this novel coronavirus, instead of tackling any of the issues suggested in the letters that I have sent to you this week, we are examining a whistleblower complaint that is only 1 week old before a proper investigation. In these letters, I will find the importance of addressing the strategic national stockpile, COVID-19's impact on mental health, testing. Certainly, we should have a hearing on testing, racial disparities and provider relief. Lack of attention to these details is detrimental to our Nation's overall response to this pandemic, and it is the responsibility of this House and the responsibility of this committee. We continue to stand on the sidelines instead of becoming fully engaged.

Every whistleblower deserves to be heard. Dr. Bright has raised serious allegations and they deserve investigation. Whistleblowers must have their rights protected, and deserve to have their allegations investigated with policies and procedures that have been long-established and upheld as independent and fair.

Madam Chair, on April 23rd, CNN reported that you planned to called Dr. Bright to testify. Dr. Bright did not actually file his whistleblower complaint with the Office of

Special Counsel until Tuesday, May 5. That same day, it was announced on social media that you planned to hold a hearing, but it was not officially noticed until 2 days later. By Friday May 8, the Office of Special Counsel recommended that Dr. Bright be temporarily reinstated as director of BARDA so that he could early conduct its investigation and move forward with its usual processes of reviewing whistleblower complaints.

Despite the hearing memo, no final determination of a violation of a whistleblower statute actually has been made. Following a robust investigation process, the customary setting for a whistleblower hearing would be in our Energy and Commerce Committee under oath in the Oversight and Investigations Subcommittee. To say this hearing is premature and it is disservice to the investigations of Dr. Bright's complaint, I think, goes without saying.

You have trampled on minority rights. You would have never tolerated that when you were in the minority. You neglected the tradition of this committee and the manner this hearing was called. The number of procedural fouls committed in advance of this hearing would certainly have led the chair to foul out of multiple basketball games. Apparently in a world without sports, this subcommittee has become political sport.

More than 80,000 American lives have been lost to this pandemic. It continues to wreak havoc on our communities, not only in terms of physical health, but mental health and certainly financial health. We should be conducting a hearing on the real-time implementation of the Pandemic All-Hazards Preparedness and Advancing Innovation Act, and we should have done it in February.

As a Democratic counterpart to the primary author, Dr. Susan Brooks on this legislation, you, Madam Chair, should have a great interest in holding such a hearing.

In my district, we have seen deaths amongst young African Americans from

COVID-19. We are hearing about a new phenomenon of very young individuals who are dying from an intense inflammatory response, apparently sparked by infection with this virus.

We should hear from some of these families and medical professionals to analyze why this virus has disproportionately affected some communities, particularly minority communities.

So, I said it before, not all heroes wear capes hospitals, doctors, and other healthcare providers are on the front lines every single day battling this virus, they go to work so we can stay home, which we have done very successfully. The inability to conduct nonessential procedures in visits has led to financial harm to our hospitals and doctors. How our States and the country preparing to ease back into providing medical care? Is the distribution of provider relief fund in the CARES Act working?

These are the questions we should be asking the experts today. I appreciate Chairman Pallone's willingness to hold telephone briefings, since we all have our own questions. But let me just say, this pandemic is about the public health of our Nation. I want to thank you for your commitment to hold future hearings on the strategic national stockpile, mental health, and racial disparities. I am happy to help you set the agenda for the rest of the year. I hope you will commit to additional hearings on testing and the provider relief fund. And I request that my letters and your responses be part of the record.

I yield back.

Ms. <u>Eshoo.</u> The gentleman yields back. I think the gentleman will recall that I called for a hearing on January 30th. And on the heels of that, it was to be with Dr. Kadlec, Dr. Fauci, all the heads of our health agencies. And it was Secretary Azar that

said, They cannot come. I am the top person and when I come, they will come with me. So that was January 30th.

Mr. <u>Burgess.</u> Madam Chair, if I may. I used to go the Oversight and Government Reform -- for 2 days.

Ms. <u>Eshoo.</u> I am not finished yet, Dr. Burgess. You have written several letters to me in the last week, and I communicated to you I am happy to sit down with you to review and to come up with all the appropriate hearings that this subcommittee should hold, and we will work together on that. We have a lot of work to do. You are absolutely right, the stockpile, testing, the list is as long as Pennsylvania Avenue. So we will work together on that, rest assured.

Now, I would like to recognize the chairman of the full committee, Mr. Pallone for his 5 minutes for opening his opening statement.

The <u>Chairman.</u> Thank you, Madam Chair. And thank you, Ms. Eshoo, for initiating this hearing and putting all your energy into it so that we are here today with Dr. Bright.

We are here as part of the Energy and Commerce Committee's ongoing work to confront the largest public health and economic crisis of our lifetimes. It has been mentioned more than 80,000 Americans have lost their lives, while more than over 36 million others have lost their jobs as of today. This is a national emergency that requires every aspect of government to work together to reduce the spread of this terrible virus so we can confidently begin to reopen our economy. While this Congress and the President have worked together to enact four laws to combat the pandemic and provide economic assistance to the American people, new laws are simply not enough.

President Trump and his administration have failed to provide the consistent and

stable leadership that is necessary to guide our Nation through this public health and economic crisis. For months, the President has delivered mixed messages and misinformation to the American people, creating confusion across the Nation. Instead of showing leadership, competence, and vision in a time of crisis, the administration has abdicated its responsibility and forced States to fend for themselves and find their own way out of this pandemic.

And while States and frontline healthcare workers were pleading for personal protective equipment, testing supplies, and other resources to protect them and their patients, President Trump's response was to let States fight it out on the open market.

For months, the President has refused to develop and implement a national testing program. For months, we have been promised millions of tests were right around the corner. The promises have been hollow. Testing is better, but nowhere where it needs to be. It doesn't help that the President proclaimed about testing earlier this week, and I quote, "We have met the moment, and we have prevailed." That could not be further from the truth, Mr. President.

Dr. Rick Bright, the former director of BARDA, has come forward as a whistleblower and made serious allegations, including a lack of urgency by administration officials to respond to the virus, mismanagement, and failing to procure necessary supplies and disregard for public health and scientific integrity. His claims lie at the heart of this committee's concerns regarding the administration's response to the COVID-19 pandemic. We are here today to hear the perspective of Dr. Bright, who is positioned to discuss the administration's preparations in response to this pandemic.

Now, the failures we have seen simply cannot persist. That is why the Energy and Commerce Committee continues to conduct robust oversight, and to propose bold

legislative solutions. We have been demanding answers and information from the administration on testing, contact tracing, the supply chain, food safety and the safety of food production workers, and attempts to undermine science and public health. To date, we have yet to receive any sufficient responses from the Trump administration.

And as for legislation, Congress has already passed four major coronavirus response packages that were improved by the work of this committee. And now, with the sense of urgency this moment requires earlier this week, we propose the HEROES Act, which is to be voted on tomorrow by the full House. The HEROES Act continues our ongoing commitment to providing the healthcare resources and support needed to combat the coronavirus crisis. Our legislation will strengthen testing and contact tracing by finally requiring the administration to develop comprehensive plans with clear benchmarks and timelines and public reporting of key metrics. This will allow transparency so we can see if the Trump administration is fulfilling their promises and hold them accountable if they are not.

We also provide \$75 billion to support robust testing, contact tracing, surveillance and containment activities. This is beyond the 25 that was in the last bill. And we simply cannot beat this virus without these efforts in place. Our legislation also ensures that all COVID-19 treatments, drug and vaccines are free of cost for patients. The bill will help us shore up our public health infrastructure for the long road ahead.

Our top priority is the health and safety of the American people. The HEROES Act builds on the progress we have made and lays the foundation we will need to ease social distancing, and safely reopen the economy.

So, I just want to thank Dr. Bright for coming forward and for being here today. I want to thank you, Madam Chair, for bringing him here. And I am hopeful that this

hearing will help us better understand the failures of the Trump administration so that collectively we can find solutions that will help us finally get a handle on this virus. It is the only way we will be able to protect the American people, and safely and confidently reopen our communities.

I thank you, Madam Chair, and yield back.

Ms. <u>Eshoo.</u> The gentleman yields back. It is a pleasure to recognize the gentleman from Oregon, the ranking member of the full committee, Mr. Walden.

Mr. <u>Walden.</u> Thank you very much, Madam Chair. And before I use my time, I do have just a parliamentary question for you, if you would yield to that. Madam Chair?

Ms. Eshoo. State your parliamentary inquiry.

Mr. Walden. So I know we are operating under really unusual conditions --

Ms. <u>Eshoo.</u> We are.

Mr. <u>Walden.</u> -- because of the masks and everything else, which is also affects the layout of the room. I know when we do oversight and investigation hearings, and I know that is not what we are doing here, there is script about whether an individual is accompanied by counsel, whether they want that counsel represented. I have got that script. The reason I am asking is we are not in O&I, but it is extraordinarily unusual to have a government witness as an individual with private counsel at the witness table and with a microphone. And so, I am just trying to get clarification for future precedent setting for the committee. And that is the only reason I am asking this, he obviously has counsel. If we should follow the protocol that is prescribed for the Oversight and Investigations Committee in similar circumstances.

Ms. <u>Eshoo.</u> Well, I think this is the first time that it is --

Mr. Walden. That is why I ask.

Ms. <u>Eshoo.</u> We have another first here. When Dr. Bright came in this morning with his attorney, she requested a microphone. And so, as a courtesy, I extended the microphone to her.

Mr. Walden. Yeah, sure.

Ms. <u>Eshoo.</u> Now, she is not a witness. We are not going to ask her questions. She is simply accompanying her client. So I don't --

Mr. <u>Walden.</u> And I have no objection to any of that. Could I read you what this text is and maybe that resolves it?

Ms. <u>Eshoo.</u> Well this isn't O&I. This is -- are you suggesting that we need to follow what O&I does?

Mr. <u>Walden.</u> I am just saying that the witness is not here in his whistleblowing capacity is what I am told, what you indicated. But this is his personal attorney, if I understand correctly, but we still don't even know for sure -- I know who you are, but we haven't identified that for the record. And all we do in O&I, as you know, is, you ask if the witness wants to be accompanied by counsel; they respond yes or no. And then counsel is allowed to move forward, sit at the table. And then the question is asked, Will you give testimony or not? And if so, raise your hand and do all these things. That is all I am doing here is just -- we don't usually do this type of activity in this -- in the other policy committees. And we are not usually set up this way --

Ms. Eshoo. So would you like to ask the --

Mr. <u>Walden.</u> I just think we ought to follow for future precedent issues, nothing to do with this hearing, but future precedent is what we are dealing with.

Ms. <u>Eshoo.</u> It is a good suggestion.

Mr. Walden. We are all learning how to operate in this environment.

Ms. Eshoo. Exactly.

All right. The gentleman is recognized for his 5 minutes for an opening statement.

Mr. Walden. Well --

Ms. <u>Eshoo.</u> You don't think it is resolved?

Mr. <u>Walden.</u> Well, are we going to ask if he wants to be represented by counsel, and who the counsel is.

Ms. Eshoo. Dr. Bright, do you wish to be represented by counsel?

Mr. Bright. Yes.

Mr. Walden. Okay. And then could she identify herself for the record?

Ms. <u>Eshoo.</u> And for the record, would counsel please state your name?

Ms. <u>Katz.</u> My name is Debra Katz. I am an attorney representing Dr. Rick Bright, with the law firm of Katz, Marshall & Banks.

Mr. Walden. All right. I think that is all we needed to do.

Ms. Eshoo. Good.

Mr. Bucshon. Could I ask --

Ms. Eshoo. The gentleman is recognized for --

Mr. Walden. Well, you have a parliamentary question.

Ms. <u>Eshoo.</u> The gentleman will state his parliamentary.

Mr. <u>Bucshon.</u> Will the witness be under oath, because if you have a whistleblower testimony under O&I, a witness would normally be under oath. And if not today, he is under -- not under oath, if we get into whistleblower allegations, how can we be sure that the witness is telling the truth under oath if they are not under oath? And if they are not under oath, then how can you talk about the whistleblower

complaints?

Ms. Eshoo. I thank the gentleman.

Mr. Bucshon. In a fair and equitable manner.

Ms. <u>Eshoo.</u> I thank the gentleman for his inquiry. All witnesses know that it is illegal to lie to Congress. And in our subcommittee, unlike O&I, they are the only subcommittee that -- I mean, it is a practice, it is a tradition, but we don't swear people in, but witnesses know that it is illegal it lie to Congress.

Mr. Walden. U.S.C. 1003 or something.

Ms. <u>Eshoo.</u> The gentleman is recognized for his 5 minutes opening.

Mr. <u>Walden.</u> Thank you, Madam Chair. And I know we are operating under unique circumstances.

The world is coping with an historic deadly pandemic that we always knew was possible, but we prayed would not happen. In a bipartisan way, we did everything the experts said we needed to do to be prepared, should a pandemic or other hazard strike.

Madam Chair, the work you, Dr. Burgess, Representative Susan Brooks, and I, and others did over two Congresses, when each party has controlled the House resulted in one product, the Pandemic All-Hazards Preparedness Act.

Dr. Bright, I know you were part of our efforts in writing and reauthorizing that law, and we thank you for your work. In fact, given the role you once played at ASPR before going to BARDA, you had a big responsibility to make sure Congress provided the strategic national stockpile that it needed, or to inform us if there were shortcomings, especially as we were modernizing the Pandemic All-Hazards Preparedness Act.

I went back over three hearings we held in the Oversight Investigations

Subcommittee of this committee, where you testified regarding the Zika outbreak in May

23rd of 2017, the seasonal flu on March 8, 2018, and the hearing on June 15, 2018 entitled the State of U.S. Public Health Biopreparedness Responding to Biological Attacks, Pandemics and Emerging Infectious Disease Outbreaks. You see, I wanted to make sure we hadn't missed anything. Nothing jumped out at me as I reread the record. Congress dramatically increased funding to ASPR and BARDA.

We granted new authorities, we followed your recommendations and those of others who played a key role in this combined effort. Unfortunately, some of the systems we put in place to prepare for a pandemic, systems designed without actually living through something like this have not performed as expected. We have learned we didn't have enough of the basic supplies that we have always taken for granted. And while Chair Eshoo and I have warned about the potential vulnerabilities of our medical supply chains, especially from China, not enough was done to address the problem, and it still hasn't been fully addressed.

I am thankful that President Trump invoked the Defense Production Act to ramp up U.S. manufacturing of masks and ventilators. And the President has used the emergency powers and money Congress has provided to launch unprecedented efforts to search the globe for supplies, to rapidly advance development of treatments and vaccines, though we still have much bipartisan work to do to respond and adapt to the challenges presented by COVID-19 and the lessons we are learning.

We have asked for, and this committee should hold hearings to find a path forward to reform the Strategic National Stockpile, to increase domestic manufacturing of critical supplies and disentangle our supply chains from China. We should be exploring strategies for increased testing so we can begin to safely reopen our economy. We need to find ways to improve access to mental health and provide relief, both for our healthcare providers on the front lines treating COVID-19 cases, and our healthcare workers who have been furloughed because their hospitals are closed. We should be conducting rigorous oversight of the trillions of dollars, and myriad of new policies Congress has appropriated and enacted in the last 3 months. And we should be investigating, really investigating, allegations like Dr. Bright's that that raise concern that

about our Nation's coronavirus response.

That does not appear to be why we are actually here today, and frankly, it saddens me. Dr. Bright, your allegations are serious. They deserve a real investigation. I know the Office of Special Counsel, with whom you filed your complaint, will do just that. And I know they take their work seriously and will hear you out. And importantly, will give those named in your complaint an opportunity to have their side heard as well.

I must tell you that many of us on our committee were confused when we learned from a tweet this hearing was scheduled in the wake of your complaint. As you know, that is certainly not how we do things at the Energy and Commerce Committee. Not long after the notice of this being a whistleblower hearing, we were advised you were here as a government witness, not a whistleblower. But then we were told you were not representing the government, but yourself.

The hearing title suggests the hearing is about protecting scientific integrity, yet the chair invited a witness who will not be speaking to that issue. So it is all pretty confusing and unusual, to say the least.

Here we are in the middle of a pandemic, and we aren't given time to secure our witnesses, conduct appropriate research or required documents that could aid in our understanding of the situation you face and the country faces.

Our first discussion with majority unfortunately just occurred 3 days ago. This is really serious business. But, in my opinion, this is not the way we should run an investigation. We need to get to the heart of the matter, and we need to look forward to see what haven't we done right as a Congress and a country, and what can we band together and fix before fall arrives?

And so, I thank you for being here. I have enjoyed working with you over the

years, and continue to look forward to working with you and others to get this right.

And Madam Chair, we have a letter for you asking for a rule 11 hearing that we will provide to you. And with that, I yield back.

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Ms. Eshoo. Thank you. The gentleman yields back.

The chair would like to remind members that pursuant to committee rules, all members' written opening statements will be made part of the record.

I would now like to introduce our witness, the first panel today. Dr. Rick Bright is a highly regarded scientist with expertise in the fields of immunology, therapeutics, vaccine, and diagnostic development. For the last decade, he has been a career civil servant at the Department of Health and Human Services. In 2016, Dr. Bright was appointed the director of BARDA, the third director of BARDA, the Biomedical Advanced Research and Development Authority. As director of BARDA, he has testified before Congress as a government expert numerous times, including before this subcommittee.

I share a special pride with Senator Richard Burr, because together, it was our legislation that created BARDA. So thank you for your willingness to join us today and to offer testimony, Dr. Bright. We look forward to your testimony. You are certainly familiar with the lights. I don't need to explain those to you. You have 5 minutes for your statement. Welcome and you have the microphone on? There we go. Good morning to you.

STATEMENT OF RICHARD A. BRIGHT, PH.D.

SENIOR ADVISOR, NATIONAL INSTITUTES OF HEALTH

Dr. <u>Bright.</u> Good morning, Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the subcommittee. I am Dr. Rick Bright, a career public servant, and a scientist, who has spent 25 years of my career focused on addressing pandemic outbreaks. I have a bachelor's degree in biology and physical sciences, and a Ph.D. in immunology and molecular pathogenesis. I have lead teams of scientists developing drugs, vaccines, and diagnostics in government, private industry and for nonprofit organizations. I am here today in my private capacity. The views are my own and not those of the Department of Health and Human Services.

I joined BARDA in 2010, and for the last 3-1/2 years, until April 21st of this year, I had the privilege of serving as its director. BARDA partners with private industry and others in government to address national health security threats.

Today, the world is confronting a public health emergency unlike any we have seen in over a century. We are facing a highly transmissible and deadly virus, which not only claims lives, but also disrupts the very foundations of our society. The American healthcare system is being taxed to the limit. Our economy is spiraling downward and our population is being paralyzed by fear, stemming from a lack of a coordinated response, and a dearth of accurate, clear communication about the path forward.

Americans yearn to get back to work, to open their businesses and to provide for their families. I get that. However, what we do must be done carefully, and with guidance from the best scientific minds.

Our window of opportunity is closing. If we fail to improve our response now

based on science, I fear the pandemic will get worse and be prolonged. There will be likely a resurgence of COVID-19 this fall, and it will be greatly compounded by the challenges of seasonal influenza. Without better planning, 2020 could be the darkest winter in modern history.

First and foremost, we need to be truthful with the American people. Americans deserve the truth. The truth must be based on science. We have the world's greatest scientists. Let us lead. Let us speak without fear of retribution. We must listen. Each of us can and must do our part now.

On Tuesday, Dr. Fauci delivered a message in a voice that is clear and trustworthy, that has encouraged us to act with caution as we return to our daily lives. We should listen to him and other scientists sharing their expertise.

While waiting for a cure and a vaccine, which I believe will come, there are things we must do immediately. We must increase the public education about the basics, washing hands, social distancing, appropriate face covering. They are simple, but critical steps to buy valuable time until there is a vaccine. We need to ramp up production of essential equipment and supplies, including raw materials and critical components, shortages of these increase the risk of our frontline healthcare workers, and they deserve the best equipment to protect themselves.

We need to facilitate equitable distribution of essential equipment and supplies.

And finally, we need a national testing strategy. The virus is here, it is everywhere.

We need to be able to find it, isolate it and stop it. We need to have the right testing for everyone who needs it. We need to be able to trace contacts, isolate, quarantine, and appropriately, while striving to develop a cure.

Initially, our Nation was not as prepared as we should have been, as we could

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on the Committee's website as soon as it is available.

have been. Some scientists raised early warning signals that were overlooked, and

pages from our pandemic playbook were ignored by some in leadership. There will be

plenty of time to look back to assess what has happened so we can improve. But right

now, we need to focus on getting things right going forward. We need a comprehensive

plan that everyone knows and everyone participates in. Congress has taken important

steps to support the response, and there is much more we can do. With your help, we

can get through this crisis.

Working cooperatively with our global partners, we can and will succeed in finding

a cure for COVID-19, but that success depends on what we do today. We will either be

remembered for what we did, or for what we failed do to address this crisis. I call on all

of us to act. To ensure the health, safety and prosperity of all Americans. You can

count on me to do my part.

Thank you.

[The statement of Dr. Bright follows:]

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Ms. Eshoo. Thank you, Dr. Bright.

We will now move to member questions. And I recognize myself for 5 minutes for questions.

Thank you again, Dr. Bright. You have a distinguished career. You are one of our country's leading public health experts on how to respond to pandemics and national security health threats. You are the first government official who has been on the inside, seeing everything firsthand, to come forward and share unvarnished experiences about what really happened from January to the time you departed BARDA in April of this year in dealing with the virus. So I want to make sure I understand what you are telling us.

You stated in your written testimony a window of opportunity is closing, but it is not yet closed. What do we need to do with the time left to get it right? And if we don't, what do you mean when you say 2020 will be the darkest winter in modern history?

Dr. Bright. Chairwoman Eshoo, thank you for your question.

The window is closing to address this pandemic because we still do not have a standard centralized coordinated plan to take our Nation through this response. I believe, with proper leadership and collaboration across government, with the best science leading the way, we can devise a comprehensive strategy. We can devise a plan that includes all Americans and help them help us guide us through this pandemic. But time is running out, because the virus is still spreading everywhere. People are getting restless to leave their homes. And we have to make critical decisions on how to balance the economy and science.

My concern about this fall is compounded by my knowledge, and preparation, and

response to many years of influenza outbreaks, pandemic influenza outbreaks and seasonal influenza outbreaks. In our country in 2017, we had nearly 79,000 people die in the U.S. from influenza. That, coupled with a COVID-19 resurgence this fall, could be devastating for our healthcare systems and for Americans. We have a limited window of opportunity to get plans in place to address both of those.

Ms. Eshoo. Thank you.

When you look at the first 4 months of this year, would you describe the government's and the administration's response as a success or a failure?

Dr. <u>Bright.</u> I believe we could have done better. I believe there are critical steps that we did not take in time.

Ms. <u>Eshoo.</u> Was there a failure to respond when you correctly pushed to claim early virus samples from -- or to obtain early virus samples from China so we could develop critical medical countermeasures?

Dr. <u>Bright.</u> From my perspective in working with companies that develop drugs and vaccines and diagnostics, virus samples are critical. As soon as we were aware this virus could pose a significant threat to human lives, I began pushing for those virus samples, and I met frustration and --

Ms. Eshoo. And when did you do that?

Dr. <u>Bright.</u> I did that in the Office of Secretary Azar in January. The push for the virus samples initially mentioned on January 23rd and a strong push on January 27th for those virus samples.

Ms. <u>Eshoo.</u> And was there a failure to respond with the needed urgency when you correctly pushed to ramp up production of masks, respirators, syringes, swabs?

Dr. Bright. Congresswoman, we have known for quite some time that our

stockpile is insufficient in having those critical personal protective equipment. So once this virus began spreading and became known to be a threat, I did feel quite concerned that we didn't have those supplies, and I began pushing urgently in January, along with some industry colleagues as well. And those urges, those alarms were not responded to with action.

Ms. <u>Eshoo.</u> Was there a failure to take immediate action when you correctly pushed to acquire additional doses of the drug, remdesivir, which is the only drug so far that appears to be at least mildly effective, thank God, for treating people with COVID-19?

Dr. <u>Bright.</u> There was no action taken on the urgency to come up with a plan for acquisition of limited doses of remdesivir, nor to distribute those limited doses of remdesivir once we had the scientific data to support their use for people infected with this virus.

Ms. <u>Eshoo.</u> And instead of acting on your recommendations, was the response of others to try and cut you out of key meetings, marginalize your participation?

Dr. <u>Bright.</u> I was told that my urgings were causing a commotion and I was removed from those meetings.

Ms. Eshoo. My time has expired.

I now recognize the gentleman, the ranking member of the subcommittee, Dr. Burgess.

Mr. Burgess. I thank the chair.

Dr. Bright, I hope that it is clear to you that everyone on this dais on both sides appreciates you coming before today, even if we are frustrated we are having this hearing without a full understanding of the facts. Again, and just to clarify, you are testifying in

personal capacity and not on behalf of the agency or the administration?

Dr. Bright. That is correct, sir.

Mr. <u>Burgess.</u> Thank you for that.

Let me ask you about question about hydroxychloroquine, really even maybe a little bit more broadly, the disease modifying antirheumatic drugs that have been looked at for therapy for this disease. I ask about hydroxychloroquine, because it does seem to be central to whatever disagreement you had with Department of HHS and the administration, but hydroxychloroquine was initially identified as a potential therapeutic because, number one, of its anti-inflammatory effects, and its ability to calm things in the immune system. As we know, one the features of this disease is the overwhelming cytacon response that overwhelms the host. There also may be an effect to blocking the virus at the point of contact with the cell, certainly something that probably deserves a little investigation.

Again, it is not the only one. There were some other drugs. I think, if I am correct, BARDA supported with its investments Actemra and Kevzara, which are thought to have similar impacts on the ability to suppress the cytacon response is hydroxychloroguine. Am I correct in that?

Dr. <u>Bright.</u> There are a number of drugs that we were evaluating initially, Congressman, that we were considering to conduct clinical studies to get further information that they really had an impact, and if they were safe to use in patients infected with this virus.

Mr. <u>Burgess.</u> Do you have available to you the dollar amounts that BARDA appropriated or authorized for each of those two drugs, Actemra and Kevzara?

Dr. Bright. I don't have those numbers available with me now.

Mr. Burgess. Would you be able to make them available to the committee?

Dr. <u>Bright.</u> I believe HHS could make those available, BARDA could probably make those investments available.

Mr. <u>Burgess.</u> Were you concerned with hydroxychloroquine at the time you made those awards for Actemra and Kevzara, or was the concern with hydroxychloroquine, which became paramount in your disagreement with the administration, was it already established when you made these other investments in similar medications?

Dr. <u>Bright.</u> My concerns around the safety of hydroxychloroquine in people infected with the COVID-19 virus reflective of the scientist review that we received from an interagency group of clinicians and regulatory experts and scientists. At the time that we learned about hydroxychloroquine and chloroquine, there was limited data available. And our proposal and actions were to see if we could identify a source of that drug so that NIH could conduct a randomized controlled clinical study.

That is a similar action we took with remdesivir. Once we thought remdesivir had promise from data coming from China, NIH quickly established a clinical study, a randomized controlled study to evaluate remdesivir. So with hydroxychloroquine, that was also our preferred plan of action.

Mr. <u>Burgess.</u> And you, of course, authored the letter to the FDA asking for the emergency use authorization for hydroxychloroquine?

Dr. <u>Bright.</u> I was directed, as the BARDA director from the Office of the HHS Secretary, to put in place an expanded access ID program to make chloroquine donation from Bayer available to Americans through a unique opportunity that would utilize an app, and perhaps make it available to Americans were not under close supervision of a

healthcare provider. During that --

Mr. <u>Burgess.</u> Of course, this hearing is not really a hearing on hydroxychloroquine. I would personally welcome a robust hearing on therapeutics and the research that is going on, what we have invested in, what seems to be panning out, what has not. I will note that both Kevzara and the other medication may not have panned out. And I think the manufacturing company for Kevzara announced that they will discontinue part of the clinical study because it looked unlikely to help Covid patients. I will tell you that since starting this, since you identified yourself for this hearing got noticed, I am hearing from a lot of doctors, my State and around the country, who have experience using hydroxychloroquine and chloroquine, coupled with Erythromycin and zinc, and they are reporting significant benefit if it is used early enough in the course, and may eliminate the need for hospitalization and ventilatory support.

Ms. Eshoo. The gentleman's time has expired.

Mr. Burgess. I don't think it is right.

Ms. Eshoo. The gentleman's time has expired.

Mr. <u>Burgess.</u> But I think it is important enough that we should look into it and would just be interested if you did that as part of your duties at BARDA.

Ms. Eshoo. The gentleman's time has expired.

Mr. <u>Burgess.</u> Can the gentleman answer the question?

Ms. Eshoo. The chair now recognizes --

Mr. Burgess. Will the witnesses be able to answer the question?

Dr. <u>Bright.</u> Sir, I believe it is important. I have heard those anecdotal stories well, and they were not conducted in the context of randomized controlled clinical study. It is very difficult to understand data from those types of observational studies or

anecdotal stories. So the drug might have some benefit in some populations, but we won't know that until we have that information from a truly randomized, controlled clinical study.

Many of those studies are ongoing now. Some of those studies we are starting to see data from and those studies in those populations tested have not shown overwhelming evidence of benefit from the use of hydroxychloroquine in those patients, but different studies are devised to look at different angles, as you described.

Mr. Burgess. Most studies are at the end, when someone --

Ms. <u>Eshoo.</u> The gentleman's time has expired.

Mr. <u>Burgess.</u> You do those studies without the drug, though. When you acquire the drug to perform the studies --

Ms. <u>Eshoo.</u> The gentleman's time has expired. The gentlemen's time, please. We all want to be fair to each other. The gentleman's time has expired.

The chair recognizes the chairman of the full committee, Mr. Pallone, for his 5 minutes of questions.

The Chairman. Thank you, Madam Chair.

Let me just say, Dr. Bright, thank you for your courage in being here. When I was younger, we used to read a book by President Kennedy called Profiles in Courage. And your courage in being here reminds me of some of the people I read about in that book.

I am concerned, Dr. Bright, that the Trump administration does not have plans for a nationwide vaccine program to ensure that once a vaccine is approved, we will be able to quickly make it available to everyone. In other words, I don't want to see the same mistakes by the Trump administration, the incompetence that they had with the supply chain and the testing repeated with the vaccine. And you stated at the outset of the

pandemic in January, you began urgently pressing HHS officials to provide the necessary resources to begin vaccine development after your pleas fell on deaf ears. And as the pandemic progressed, you also stated you were alarmed by the pressures coming from some administration officials for your agency to invest in drugs and vaccines, and I quote, "without proper scientific vetting or that lacked scientific merit." Can you tell us where we are now in the hunt for a vaccine and where we could have been, had the HHS leaders made investment decisions sooner that were based on scientific merit?

Dr. Bright. Thank you, Congressman.

As we all know, vaccines are very difficult to make. It is nothing they can do quickly and you need multiple shots on goal to try to make a vaccine. There are many diseases, we have attempted to make vaccines through history and still haven't been able to do so. So it takes many opportunities and many different approaches. Right now, there are over 100 different approaches for developing a vaccine for this coronavirus. So we are confident that hopefully, I should say, at least one of those or two of those will work. But you have identified key critical challenges that we need to anticipate and prepare for early. Number one is the supply chain for those vaccines, needed reagents and buffers and salts, and the various ingredients go into a vaccine, as well as the glass vials that the vaccines are put into, and needles and syringes, and then a carefully coordinated distribution and administration strategy.

We haven't yet gotten to those downstream strategies yet in our government.

And I think those are going to become a significant issue down the road if we don't plan for that now.

The urgent need for funding at the outset of a pandemic is something we have known about through many years of pandemic exercises. Even in our August 2019

Crimson Contagion exercise, it was highlighted that we would need at least \$10 billion from the outset of the pandemic to start the development of drugs and vaccines. Every day we delay delays the output of that vaccine or drug. So in those early days, my first meetings with Secretary Azar, I asked for funding for people and for those viruses, the three critical things to get the vaccine started.

It took some time to get the funding available through various processes. What BARDA did is we began to look internally at other contracts and other programs we had to redirect some available fundings and minimal funding to even as early as January, be able to initiate contracts or agreements with some companies to start working on those vaccines as soon as possible. It is because of those actions now that not only have those vaccines started and made some progress, but also, the United States has a placeholder with some of those companies to be able to place orders for those vaccines when they are available. We did everything possible to ensure that those investments were in companies that would build capacity in the United States to manufacture those vaccines. We had to get in line first, even when the money wasn't fully there, to complete the development program, that is what we did.

The <u>Chairman</u>. I guess my concern is, I am very critical of the administration in terms of their, I call it incompetence with the supply chain, with lack of testing. I am afraid the same thing is going to happen with vaccines and the distribution. I mean, should I be concerned based on your experience?

Dr. <u>Bright.</u> Absolutely, sir. We are already seeing those challenges with limited doses of remdesivir with data that we are getting that remdesivir has some benefit in people. And we have limited doses, and we haven't scaled up production, and we don't have a plan in how to fairly and equitably distribute that drug. If you can imagine the

scenario this fall or winter, maybe even early next spring, when a vaccine becomes available, there is no one company that can produce enough for our country or for the world. There will be limited supplies. We need to have a strategy and plan in place now to make sure that we cannot only fill that vaccine, make it, distribute it, but administer it in a fair and equitable plan.

The Chairman. And that is not the case?

Dr. Bright. We don't have that yet, and it is a significant concern.

The Chairman. Thank you. Thank you, Madam Chair.

Ms. <u>Eshoo.</u> The gentleman yields back. I now have the pleasure of recognizing the ranking member of full committee, Mr. Walden.

Mr. <u>Walden.</u> Thank you, Madam Chair. And again, I thank the witness for being here.

I want to get some clarification. So BARDA's job is to do the vaccines, right?

Dr. <u>Bright.</u> That is one of BARDA's roles, yes, to support industry to make the vaccines.

Mr. <u>Walden.</u> Okay. Is it BARDA's responsibility to direct the personal protective equipment acquisition distribution, the PPE? Is that part of your responsibility at BARDA?

Dr. <u>Bright.</u> BARDA plays a role in pandemic preparedness for our Nation. And we prepare and align and exercise with our other Federal agencies. We also are familiar with the critical gaps in the supply chain. While BARDA isn't responsible for procuring those items for the Strategic National Stockpile, we are aware of those shortages and those needs. What I was doing in my capacity as BARDA director was raising those concerns and needs with the appropriate group within ASPR, the strategic national --

Mr. <u>Walden.</u> But ASPR basically has a responsibility to go do that, right? That is not your direct responsibility. You are obviously in this discussion, but that is not how it was right in BARDA, correct?

Dr. <u>Bright.</u> It is my responsibility to raise a significant concern about a limited supply or shortage that I think will affect the lives of Americans?

Mr. <u>Walden.</u> Did you raise that concern with people up here on Capitol Hill? And if so, who and when?

Dr. <u>Bright.</u> I raised that concern with my leadership, sir. I raised it with the appropriate folks in the Strategic National Stockpile and our Critical Infrastructure Protection Program.

Mr. Walden. Not up here?

Dr. <u>Bright.</u> My role is to raise it to my supervisor, Dr. Kadlec. I also did raise that concern, though, in the White House with Mr. Navarro.

Mr. <u>Walden.</u> Yeah, I am interested, because we are passing these bills. In the future, I hope you would or anybody out there listening in these agencies, if you are spotting something not working right, we need to know.

Dr. Bright. Yes, sir.

Mr. <u>Walden.</u> On the first case of SARS COVID 2 in the U.S., it was identified, I believe, in January 22, in Washington State. CDC put the positive specimen in culture that day, correct?

Dr. Bright. I believe so. I think it was January 20th.

Mr. <u>Walden.</u> Okay. It is my understanding, the samples of the virus were made available to the U.S. Government and that the CDC expanded the virus stocks between January 29 and February 3 and shared the BEI on February 4 to enable broad sharing.

Now, according to your complaint, after virus samples were available to the U.S. government from the Washington State case, and potentially even after the CDC's effort to grow the virus and then share with the BEI biorepository, you were still seeking to obtain a sample of the virus, correct?

Dr. Bright. That is true, sir. But we need more than one virus.

Mr. <u>Walden.</u> Right. I am going to get to that. Why were the strains not available within the U.S. Government, not available to you? Were they available to you?

Dr. <u>Bright.</u> Sir, I was asking for viruses in January because we wanted to make sure that we had a head start on developing the vaccine.

Mr. Walden. No, I get that.

Dr. <u>Bright.</u> When they became available in February, I believe it was February 6 through the BEI resources, then those were distributed to laboratories.

Mr. <u>Walden.</u> Did you ask for the virus sample from Washington State, though, as part of that?

Dr. Bright. Absolutely.

Mr. Walden. You did?

Dr. <u>Bright.</u> BARDA did. We asked to make sure we had access to those viruses, and they were distributed to the right laboratories and the right companies.

Mr. Walden. And where did you ultimately get the virus that you distributed?

Dr. <u>Bright.</u> Some of the viruses came from the BEI resources at NIH, and some of those viruses came from laboratories that receive the initial seed from CDC.

Mr. Walden. Okay, That is helpful to know.

In some conversations I have been a part of with some at NIH, they indicate that the real key here was to get the DNA sequence, which China did eventually put up, I

believe, the end of December, early January, and that in terms of going after the vaccine, it was that sequencing that really mattered most to get started on vaccine development. And there are other scientists who are very distinguished who believe that the delay in getting the virus sample actually didn't set them back. Is that an accurate assessment, or do you have a disagreement in that view? I know scientists disagree, so do we up here. But I am kind of hearing that having the sequencing really mattered most -- and getting the virus important, but did not set them back in proceeding to get the vaccine development underway.

Dr. <u>Bright.</u> Sir, China posted the first sequence on January 11, I believe and made it available January 10 or January 11. It is important to understand that when the sequence is available, some companies, or some technologies, can get started with that sequence information. You still are vulnerable because you have another country in their laboratories that post on the internet or database their sequence. So there could still be challenges, especially for national security integrity for that sequence.

Mr. <u>Walden.</u> Before my time runs out -- well, it has run out. I was just going to ask, did they begin efforts at that time once they got the sequence?

Dr. <u>Bright.</u> The NIH began efforts on a synthetic messenger RNA vaccine candidate. However, without the viruses, you really cannot tell if the neutralizing antibodies listed by that --

Mr. Walden. Right.

Dr. <u>Bright.</u> -- or your, diagnostics, or your therapeutics that actually work. You can try to synthesize a virus a sequence, but it is never going to be representative of the actual virus. And when we are spending billions of dollars on drugs, vaccines, and diagnostics, we want to have the most credible information possible.

Mr. Walden. Thank you, Madam Chair.

RPTR MOLNAR

EDTR CRYSTAL

[11:03 a.m.]

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentleman from New York, Mr. Engel, for his 5 minutes of questions.

Mr. Engel. Thank you, Madam Chair, for holding today's hearing.

Doctor, if you were a betting man -- oh, sorry. Thank you.

Doctor, if you were a betting man, when would you bet that we would -- time that we would have a vaccine?

Dr. <u>Bright.</u> That is a very difficult question to answer. I know that there are companies and academic labs working very hard.

Normally it takes up to 10 years to make a vaccine. We have done it faster in emergency situations, when we had the starting material in the freezer for Ebola. But for a novel virus, it actually haven't been done yet that quickly.

So a lot of optimism is swirling around a 12- to 18-month timeframe if everything goes perfectly. We have never seen everything go perfectly.

My concern is if we rush too quickly and consider cutting out critical steps, we may not have a full assessment of the safety of that vaccine. So it is still going to take some time. I still think 12 to 18 months is an aggressive schedule, and I think it is going to take longer than that to do so.

Mr. <u>Engel.</u> Twelve to 18 months from now or 12 to 18 months from when this all started, the beginning of the year?

Dr. <u>Bright.</u> It would be 12 to 18 months from when the particular manufacturers first received the material or information that they needed to start developing that

vaccine.

It is critical to note, when we say 12 to 18 months, that doesn't mean for an FDA-approved vaccine. That means to have sufficient data and information on the safety and immunogenicity, if not efficacy, to be able to use on an emergency basis, and that is the consideration that we have in mind when we talk about an accelerated timeline.

Mr. Engel. Thank you.

I represent, in New York, Bronx County and Westchester County, which are at the epicenter of the U.S. coronavirus outbreak, New Rochelle, New York. While New Yorkers have really rallied together in support of their neighbors, the administration has failed at every turn. The President has sidelined our best scientists, pushed baseless conspiracy theories, and more recently prescribed unproven remedies, like Lysol, to suffering Americans.

Since the early days of the outbreak, the President encouraged doctors to prescribe chloroquine to suffering Americans despite a lack of evidence supporting its use. On April 24th, the President's hand-picked FDA commissioner even came out against the use of chloroquine for COVID-19 cases.

Doctor, what are the dangers of chloroquine if prescribed incorrectly? And what happened when you raised the issue of chloroquine use in coronavirus patients with HHS leadership?

Dr. <u>Bright.</u> Congressman, our concerns center around the potential use of chloroquine in people who are infected with this coronavirus. There are data of the effective use and safe use of chloroquine in malaria patients and other patients and other indications. We also knew that there were potential safety risks with chloroquine that

cause irregular heart rhythms and even, in some cases, death.

So our concern was with limited information and knowledge, especially of its use in COVID-19 infected patients and the potential for those at risk, then we should make sure that any studies with that drug were done in a carefully controlled clinical study under the close watchful eye of a physician so they could respond to a patient if they did experience one of those adverse events.

There wasn't sufficient data at that time to support use of this drug in patients with COVID-19 without close physician supervision.

Mr. <u>Engel.</u> And when you raised that issue of chloroquine use in coronavirus patients with HHS leadership, what happened to you? You were removed as the director of BARDA, is that not true?

Dr. <u>Bright.</u> I believe part of the removal process for me was initiated because of a pushback that I gave when they asked me to put in place an expanded access protocol that would make chloroquine more freely available to Americans that were not under the close supervision of a physician and may not even be confirmed to be infected with the coronavirus.

The scientists at FDA, BARDA, NIH, and CDC worked hard to switch that to an emergency use authorization with strict guardrails: that the patients would be in a hospital, confirmed to be infected with this virus, under close supervision of a doctor, and who could not otherwise participate in a randomized controlled study.

My concerns were alleviated somewhat by being able to lock that in the stockpile with those conditions. However, my concerns were escalated when I learned that leadership in the Department of Health and Human Services were pushing to make that drug available outside of this emergency use authorization, to flood New York and New

Jersey with this drug regardless of the EUA.

And when I spoke outside of our government and shared my concerns for the American public, that, I believe, was the straw that broke the camel's back and escalated my removal.

Mr. Engel. Thank you.

Thank you, Madam Chair.

Ms. <u>Eshoo.</u> The gentleman's time has expired. A pleasure to recognize the gentleman from Kentucky, Mr. Guthrie, for his 5 minutes of questions.

Mr. <u>Guthrie.</u> Thank you very much.

Thank you, Dr. Bright, for being here. We appreciate it very much.

Reading through your complaint, I just kind of want to point out, I think the chairman said earlier, talked about the lack of urgency, and implies the President's lack of urgency. I think most of my constituents want to know that things are getting done and where is the President on this.

And you are having issues with the leadership at Health and Human Services, and you are giving them recommendations. So if they are not accepting your recommendations to them, I would, I think, fairly surmise, they are not passing that on to the White House.

So the President is probably unaware of what you are putting forth because it says, in reading from your complaint on page 23: "Fortunately, White House Trade Advisor Peter Navarro shared Dr. Bright's sense of urgency." So that is a sense of urgency.

So talking about the urgency in the White House. So you have a meeting with him on Saturday. He calls you back in on Sunday. You prepare your recommendations

in a memo for Mick Mulvaney, Chief of Staff, so essentially the President.

And then -- so you meet with -- you get around the leadership of HHS, meet essentially with the President, since with Mick Mulvaney, and it says -- you have the meeting with Navarro on Saturday, the memorandum with Mick Mulvaney on Sunday, and on Monday, it says, the National Security Council Policy Coordinating Committee met with Doctor -- "met and directed Dr. Kadlec and HHS to implement Navarro's recommendations. The push by the White House for HHS to act more swiftly created tension between Dr. Bright and HHS political leadership."

So it seems -- I don't know how you could be more urgent in government than having a meeting on Saturday, a memorandum on Sunday, and actions on Monday once it got to the President's attention, the President's level. So we appreciate the President moving forward on that.

I am on -- the ranking member of O&I, the investigations, which you have testified in front of us before, and we appreciate that very much. So I am going to look at more of the process of putting this hearing together and some things.

As we read through your complaint, the only way we have it is because you made it public. And in your complaint, there are different exhibits that you talk about, and we are having a hearing today, and there are actually 33 exhibits referenced in your complaint that is not public. I think we got them from -- the majority through The Washington Post or something like that. That is how we were made documents available for this hearing, my understanding.

So the 33 exhibits that are not made public that are referenced in your complaint, would you make those available to the committee?

Dr. Bright. [Off mic.]

Mr. <u>Guthrie.</u> Do you have those to make them available to the committee? [Witness consults with counsel.]

Mr. <u>Guthrie.</u> I mean, if we are using your complaint for this hearing, we need to have the documentation.

Ms. <u>Katz.</u> May I address that?

Mr. Guthrie. If the chair -- I don't have a problem with you addressing --

Ms. Eshoo. [Inaudible.]

Ms. <u>Katz.</u> Yes, we will take that under advisement and get back to you.

Mr. <u>Guthrie</u>. Okay. Also, when we read through the --

Voice. That is not an answer.

Ms. <u>Katz.</u> There may be privacy considerations in some of the documents, so we do need to look at these documents carefully.

Mr. <u>Guthrie.</u> So also if we read through the email chains that are made available, some appear complete, but some truly aren't. They are apparently not full email chains. And so you will wonder if the context of the email would relate to the inferences taken from the emails. Would you make all the complete email chains available to us?

Ms. <u>Katz.</u> I would like to address that as well, which is a problem, is when Dr. Bright was removed from his position, he was locked out of his email. He does not have access to his full email.

Mr. Guthrie. So the email chains that you have available, we have? We have?

Ms. Katz. That is correct.

Dr. Bright. I can address --

Ms. Katz. He does not have a full set of his email.

Dr. Bright. I can address this too. That is exactly right. So I was immediately

locked out of my email on April 20th of this year, and so I didn't have full records available to me on that.

However, I believe I have laid a solid foundation in my complaint, as detailed as I could be, for the Office of Special Counsel to be able to conduct an investigation.

I believe as part of their investigation, they will be able to access those emails and individuals to get the full story and get the full information so they can get to the bottom of it.

Mr. <u>Guthrie</u>. It would have been helpful for us as well.

Have you shared any of these exhibits with the majority that has not been shared with us in the minority side?

Dr. <u>Bright.</u> Sir, I believe you have probably what is available in the public domain, and I believe the rest has been submitted to the Office of Special Counsel. And I haven't made it available to anyone directly.

Ms. <u>Eshoo.</u> To the gentleman, the minority and majority members all received the same packet of information --

Mr. <u>Guthrie.</u> Which is available to the public.

Ms. Eshoo. -- the emails, yeah --

Mr. Guthrie. Okay.

Ms. <u>Eshoo.</u> -- that was available, that was in the public domain.

Mr. Guthrie. Okay.

So just one more. Are there any other documents in your possession or accessible to you that are not included as exhibits in the complaint but are nonetheless relevant to your allegations? If so, will you provide those to the committee.

Dr. Bright. I believe I provided the information I have available to me at this

point. If I had access to my email from HHS, there might be additional supporting information in that email. I do not know the status, if that has been deleted or wiped or -- I just haven't had access to it since April --

Mr. <u>Guthrie.</u> Okay. What you have access to. I appreciate your answers. Thank you very much.

I yield back.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentleman from North Carolina, Mr. Butterfield, for his 5 minutes of questions.

Mr. <u>Butterfield.</u> Thank you, Chairwoman.

And to you, Dr. Bright, thank you, sir, for coming today, and thank you, most importantly, for your 25 years of public service.

Dr. Bright, I would like to ask you about your efforts to address supply shortages for administering COVID-19 tests.

According to your count, as COVID-19 testing ramped up, you asked for an inventory of the strategic national supply availability of testing supplies, including swabs, viral transport materials, and extraction buffers. You learned that the national stockpile did not stock these items.

After that, you learned that FDA's source of swabs was a manufacturer in the region of Italy, which was the center of the COVID-19 outbreak in Italy. It is my understanding that this information then prompted you to reach out to the DOD agency that had previously assisted your office with international transportation of supplies related to Ebola.

My question is why, why, sir, did your office contact DOD at this point?

Dr. Bright. Sir, it was quite a surprise to me that the urgent ramp-up of testing

did not include full consideration of all the critical supplies needed to support that ramp-up of testing, including those materials you mentioned -- swabs, viral transport media, buffers, et cetera. And I was quite alarmed to learn, from sitting behind CDC Director Redfield, that we were going to experience a shortage of swabs. And I was even more surprised that our Strategic National Stockpile did not plan or have any of those in supply.

So my urgency to find a solution to that was supported by the FDA director of the Center for -- CDRH, that is devices and diagnostics at FDA.

And once I confirmed that there was a shortage, it was critical that we find a solution, and that was by partnering with our Department of Defense colleagues who worked with us for the Ebola response. We actually worked with them to ship doses of Ebola vaccine from Germany to the United States so it could be filled rapidly to respond to the outbreak in Africa.

So it was a natural occurrence or response for me and my colleagues in BARDA to come up with a solution to that critical supply chain.

Mr. <u>Butterfield.</u> Let me ask you this. Were there any restrictions in place in Italy that would require Secretary Azar to move forward with the request to DOD?

Dr. <u>Bright.</u> What we needed to enact that air bridge with the Department of Defense was we needed our Secretary of -- Secretary Azar to make a request of the Secretary of Defense. And I and my colleague, Dr. Gary Disbrow, raised this issue with our -- at our senior leadership meeting with Dr. Kadlec, who chairs that meeting, the ASPR, and it clearly was not a topic that he wanted to discuss on that day. And actually we were rebuffed by him saying that he did not really want to talk about swabs right now. And both Dr. Disbrow and I raised this concern repeatedly in that call.

So knowing that it was critical and time-sensitive, and we had a critical shortage of these swabs, I placed a call to Mr. Navarro's office once again and asked if Mr. Navarro could offer some assistance in contacting the Secretary of Defense to get clearance for DOD to put those airplanes in place under the contract we have. And that happened in a very quick turnaround, a matter of minutes.

With that permission from the Secretary of Defense, we were able to start those flights within 2 days. We have now transferred back over 25 million swabs.

Mr. <u>Butterfield.</u> So you are saying that you alerted White House adviser Peter Navarro about this issue. Is that right?

Dr. Bright. Yes.

Mr. <u>Butterfield.</u> And within hours, literally within hours, he had coordinated with DOD to start these flights to transport the swabs.

Dr. Bright. Yes, sir.

Mr. <u>Butterfield.</u> This seems like a logical response to the analysis that you provided. What is truly perplexing to me is why anyone would resist such an initiative. That is a rhetorical question. I won't ask you to answer that.

Finally, we still don't have enough testing supplies. I don't understand how and why that is possible. I understand that converting an auto plant to build ventilators might take a little time, but how can we be struggling to get adequate supplies of simple supplies like swabs? What does this say about the Federal response to the coronavirus outbreak?

Dr. <u>Bright.</u> It says to me, sir, that there is no master coordinated plan on how to respond to this outbreak. We don't have a strategy or plan in place that identifies each of those critical components, and we don't have a designated agency that is sourcing

those critical components and coming up with a strategy to make sure that we have those supplies when we need them.

We need this comprehensive national strategy that is end-to-end, it includes every component to make sure we can respond and protect American lives.

Mr. <u>Butterfield.</u> Thank you, Dr. Bright. You are a great American. Thank you very much.

I yield back.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentleman from Virginia, Mr. Griffith, for his 5 minutes of questions.

Mr. Griffith. Thank you, Mr. Chair -- Madam Chairman. Appreciate that.

It seems like Mr. Navarro has done a pretty good job in listening to the questions.

I do wish we had more of the information available, and it is one of the reasons why -- it is not your fault -- but why I wish we had done this through the regular channels.

But I would ask this. On some of the questions that were just asked about supplies being available, I kind of got the impression from prior testimony that Project BioShield, which you urged us to put money into and we put \$700 million in 2018 and \$735 million in 2019, was supposed to take care of some of that. Am I misunderstanding Project BioShield?

Dr. <u>Bright.</u> Project BioShield is used to invest in late-stage development of drugs and vaccines --

Mr. Griffith. It was for the drugs.

Dr. Bright. -- primarily and some diagnostics and --

Mr. Griffith. So that didn't help on this at all?

Dr. Bright. It didn't help on this at all, sir.

Mr. <u>Griffith.</u> All right. Now, that being said -- and I did say, you know, and I would hope that we would have had everything available to us, and I understand that may not be your fault, but it does create issues. But everything is going crazy, people have all kinds of things going on, and this hydroxychloroquine comes up. And there is some email exchanges in exhibit 54 from your documents indicate that -- a Chris -- Christopher Houchens writes and he says, you know, we should probably take a look at this -- I am paraphrasing, but the line I took out of it was -- especially when we have few or no options.

One of the frustrations I have had for years with our community trying to respond to all kinds of different diseases is we want to have the double-blind studies in place, we want to have all the science there, which makes sense if you have an alternative. But when you have few or no options, it seems to me you would go after those things that are available. And if hydroxychloroquine is one at one point, then remdesivir I am assuming, have they done the double-blind studies related to COVID on remdesivir? Has that already happened?

And then I have got an article from the Richmond Times-Dispatch, April 15th, where a doctor used high doses of vitamin C and a drug called Actemra.

Also -- Actemra.

All of these are floating out there, doctors are using all kinds of things, because we don't have other options. And so I am wondering, what was the great hesitancy to at least let doctors try. And even if anecdotally it was having some effect, wouldn't you have to have that available in order to be able to do the tests? And if you have got few or no options, why wouldn't you want to go down that pathway?

Dr. Bright. We want to make sure that the drugs that we consider are safe and

effective. The highest priority is safety. So many of these studies that we had or anecdotal evidence or reports we had did not include a thorough safety vetting of those drugs.

There are some known side effects with some of the drugs. Many of these drugs were repurposed, so they weren't build de novo. So we knew about some of those potential safety concerns, and we didn't have any evidence of how those safety concerns would appear in people infected with this virus.

This virus takes over a lot of your body. It actually infects multiple organs in your body and causes significant inflammation and multi-organ shutdown in some cases before death and acute respiratory distress syndrome that really turns your lungs into a brick.

Mr. <u>Griffith.</u> It is scary stuff. And you said though on hydroxychloroquine that, you know, one of the problems was you might have an irregular heartbeat. If you are worrying about not having a heartbeat at all, that is really not -- you are not worried about irregular if you don't have one at all. Am I not correct about that?

I mean, that is the concern. People were dying out there, and here was the first one that showed some promise. Why wouldn't we want to accept, you know, an offer from a manufacturer to give us a lot of this and have it out there for widespread use, if the doctors chose, just like the doctor in Richmond?

That didn't work in that case. They actually used it there, in that case, and it didn't work, so he tried something else. I mean, I think that is really what we are going to have to do in an emergency situation. Am I not correct?

Dr. <u>Bright.</u> We need to do it carefully, sir. We have to make sure that when we have that information available with those potential drugs available, we are thinking outside the box --

Mr. Griffith. Can't we be so careful that we accidentally kill people?

Dr. <u>Bright.</u> We need to move swiftly, sir. And we have actually shown that we can put up a clinical study in the matter in less than a week.

Mr. Griffith. Okay.

Dr. <u>Bright.</u> It is important to use available clinical data. And if we know there are potential risks, we need to make sure that we are cognizant of those risks and make sure those drugs are used in a very safe and controlled manner.

Mr. Griffith. Yes, sir. And I appreciate that.

And let me just say this. You know, it is our job to ask some tough questions sometimes, but, you know, just like you found friendly ears at the White House, you might have found some friendly ears on our side of the aisle here as well.

And I would note that in 2018 you were talking about vaccines, and you were talking about offshore production. And I said, let me know what I can do to help get more production onshore. But I never heard from you.

I am happy to help. I want onshore production. I am with you on a lot of these issues. I don't know what is going on behind the scenes. We have got to investigate that. Today, unfortunately, was not the day to do that investigation. We don't have enough information. A lot of stuff is not here for us.

But don't hesitate in the future. If you see something, let us know on both sides of the aisle what is going on.

I appreciate it, and I yield back.

Dr. Bright. Thank you.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentleman from California, Ms. Matsui, for her 5 minutes of questions.

Ms. Matsui. Thank you very much, Madam Chair.

And thank you, Dr. Bright, for appearing before us today, and thank you for your public service.

Dr. Bright, you have described a series of missed opportunities that have left our country woefully unprepared for the pandemic's impact. Many Americans are eager to return to normalcy, as we can all understand. But to even begin safely reopening, we need widespread testing capacity, an organized contact tracing workforce, and a healthcare system that can handle further surge. And, ultimately, a vaccine or therapeutic cure is required.

I would like to ask you a series of questions about your warnings to the administration while at BARDA. I am hoping you can succinctly answer whether you believe each scenario will ultimately shorten or lengthen the time it takes for our country to safely reopen and recover from the coronavirus pandemic.

On January 10, you began pushing HHS leadership to obtain sequencing on virus samples. Given the importance of these samples for vaccine and diagnostic development, has the administration's inaction shortened or lengthened our timeline for reopening?

Dr. <u>Bright.</u> Those samples were critical to get started as early as possible.

There was delay in getting those samples. That means there will be delay in getting those countermeasures. Those countermeasures are critical to reopening our country.

Ms. <u>Matsui.</u> Okay. Throughout the month of January, you made HHS aware of the urgent need to increase funding to combat the virus. HHS leadership believed that BARDA's budget was sufficient. Has the delay of these resources shortened or lengthened our timeline for reopening?

Dr. <u>Bright.</u> Delay of those resources have extended the ability -- the timeline to make drugs available and vaccines, therefore, has extended our ability to respond to this pandemic.

Ms. <u>Matsui.</u> On January 18, you pushed Dr. Kadlec to coordinate COVID-19 planning activities across the government. Dr. Kadlec initially rejected your request, suggesting it was not time-sensitive. Did this delay in coordination shorten or lengthen our timeline for reopening?

Dr. <u>Bright.</u> That lengthened the timeline of our reopening. We needed those early policy discussions to happen as soon as possible.

Ms. <u>Matsui.</u> From January through March, you pushed for HHS to ramp up production of N95 masks, swabs, and syringes. HHS failed to act quickly. Has this inaction shortened or lengthened our timeline to reopening?

Dr. <u>Bright.</u> That inaction has put a lot of lives at risk in our frontline healthcare workers, and no time to reopen our country will bring those people back to us.

Ms. <u>Matsui.</u> Certainly. Thank you, Dr. Bright. Of course, there are many decisions made outside of these scenarios that influence when we can safely reopen, but from what I am hearing today, HHS, if they heeded your warnings early, we could have proactively limited the toll this pandemic has taken on our country.

It appears clear from the whistleblower report that the Trump administration prioritized political calculations above public health with regard to chloroquine and hydroxychloroquine. Despite the lack of data supporting the clinical benefits for the treatment and prevention of COVID-19, the Trump administration promoted the drug's use to the American people because it was seen as a big, immediate win.

Dr. Bright, do you believe there are other instances where the administration

relied on politics rather than science to make coronavirus response decisions? And what consequences might those decisions have had on public health?

Dr. <u>Bright.</u> We have a very rigorous scientific review process for all of the investments that we make for the drugs, vaccines, and diagnostics through BARDA and through our department actually. And so there were some attempts to bypass that rigorous vetting process that caused me great concern and actually increased the tension between me and Dr. Kadlec.

Without that scientific vetting, that does increase the risk of a drug being evaluated or supported that could have safety concerns. And we really needed to have the best scientists in our country weigh in on whether or not that drug should be evaluated and how it should be evaluated to address those safety concerns.

Ms. Matsui. Certainly.

The Trump administration waited until April to invoke the Defense Production Act to increase the production of life-saving medical supplies, like masks, months after doctors began experiencing shortages and 3 months after your initial January warnings.

Should HHS have invoked the Defense Act earlier to increase the domestic production of critical medical supplies like masks and swabs?

Dr. <u>Bright.</u> I am actually not an expert on the Defense Production Act and how it is used most effectively. I do believe that we should have been doing everything possible -- placing orders early, ramping up supply, ramping up production of those critical medical equipment -- as quickly as possible. Whether or not that is through the Defense Production Act or other mechanisms, it should have been a high priority.

Ms. <u>Matsui.</u> Okay. Well, thank you very much, Dr. Bright. I have run out of time, and thank you very much for appearing before us today.

Ms. <u>Eshoo.</u> The gentlewoman yields back. A pleasure to recognize the gentleman from Florida, Mr. Bilirakis, for his 5 minutes.

Mr. <u>Bilirakis.</u> Thank you, Madam Chair. I appreciate it very much.

And I want to thank Dr. Bright as well for your service to our country.

I have a few questions, and I am focusing on the hydroxychloroquine. When was the potential use of chloroquine and hydroxychloroquine as treatment for the COVID-19 first brought to your attention, sir?

Dr. <u>Bright.</u> I believe it was probably mid-March, between March 10th and March 17th, somewhere in that timeframe.

Mr. Bilirakis. And not prior to that?

Dr. <u>Bright.</u> Not that I recall. The first I heard of the drug itself was a call I received from Dr. Woodcock at the FDA asking if I had heard of the drug. And I hadn't heard of the drug, and I hadn't heard of its potential use for COVID-19 patients. She said there might be something interesting to look at. And she forwarded a manuscript, a draft manuscript, and that is the first I learned of the drug itself.

Mr. <u>Bilirakis.</u> So you won't -- you didn't -- you weren't aware of any news articles and research papers in January discussing the potential benefits of the drug?

Dr. Bright. I heard anecdotal stories and reports, sir.

Mr. <u>Bilirakis.</u> You had?

Dr. <u>Bright.</u> I had -- I can't recall if I did specifically for chloroquine, but I tried to track the media and the scientific journal as well. However, I rely on the guidance of the science within HHS, and the first I had heard of that was from my colleague, Dr. Woodcock, at the FDA, and then a summary report from our scientists at FDA, CDC, NIH, and BARDA, that indicated that the evidence for its benefit was weak and the

evidence for its safety concerns was stronger. And they did not believe at that point it was something that should be supported.

Mr. <u>Bilirakis.</u> Okay. Now, again, what was your reaction personally? Did you think it was something worth pursuing initially when you heard it from Dr. Woodcock?

Dr. <u>Bright.</u> Initially, I said, I do believe -- I mean, I trust Dr. Woodcock and her scientific judgment immensely, and if she mentioned it as something that we should look at and as something we should consider testing in a randomized controlled clinical study, I would be supportive of the team reviewing that protocol and that information to see if it should be used.

Mr. <u>Bilirakis.</u> Sir, you know, I understand, I have heard it from experts -- and I am certainly not an expert in this area -- that the drug, the one that we are talking about in this case, hydroxychloroquine, if it is used, first of all, timely, because I now understand there is a window there as far as the patient, the effective -- the efficacy of the drug.

Have you heard this, that if it is administered properly there is a small window there for the patient as far as risk is concerned? Can you elaborate a little bit on that if you have heard that? And again, this is not from a layperson. This is from an expert.

Dr. <u>Bright.</u> We have seen anecdotal, heard of anecdotal data from different physicians that they believe they have seen benefit or patient improvement from use of this drug in either combination with an antibiotic, azithromycin, or in combination with zinc or other -- vitamin C or other things, but there was never sufficient evidence from a randomized controlled study to show its benefit would actually outweigh the potential risk.

That is why the NIH and probably 40 other institutions around the world are conducting randomized controlled clinical studies to look at the benefit either in

late-stage treatment or early-stage treatment. Most of the data coming out from those clinical studies to date haven't shown an overwhelming level of evidence that it has benefits in those patients.

It doesn't mean that it might still have some benefit in individuals or a case or two in different studies or that physicians believe they see a benefit in their patients. But in the context of a randomized controlled study, we haven't seen an overwhelming level of benefit.

Mr. <u>Bilirakis.</u> Have you reviewed the studies in other countries, such as France and possibly Japan, on these? I mean, are you -- I just want to know, because my constituents ask these questions. Do you take those studies into consideration when you make these decisions?

Dr. <u>Bright.</u> We absolutely do. We look at the quality of those studies. We look to see if they were done with the right controls in place and the right sample size. Was it statistically relevant or was it just a few people, was it 20 people or was it 2,000 people? All of that adds to the power of the data itself.

Many of studies that we saw early only included a few number of patients, and so it was unclear, even from the description of some of those studies that were not in peer-reviewed journals, whether all the patients were treated the same, whether they had full participation throughout the clinical study itself. And looking at the statistical power of many of those studies, they were very small. So it is really difficult to understand the impact, the benefit.

We also saw a study that the VA hospital conducted with hydroxychloroquine that showed people who are treated with hydroxychloroquine appeared to have a higher rate of death than people who were not treated with hydroxychloroquine.

So that study too has weaknesses. No study is actually perfect. You take all of that evidence into account when you make a decision on how to further study the drug or how to use that drug.

Mr. <u>Bilirakis</u>. It is my understanding that, not my constituent, but a U.S. citizen who -- a veteran -- was cured -- again, this is just what I heard -- from the drug. And that was a late-stage case, but I have also heard of early-stage cases as well. So I wanted to get that on the record.

Thank you, Madam Chair.

Ms. <u>Eshoo.</u> The gentleman's time has expired. He yields back. A pleasure to recognize the gentlewoman from Florida, Ms. Castor, for her 5 minutes of questions.

Ms. Castor. Thank you, Madam Chair.

Dr. Bright, thank you for speaking out to save lives.

I read your whistleblower filing, and I want to ask you about the N95 respirators.

These respirators are essential personal protective equipment. They are not the cloth mask or surgical masks that everyday Americans are encouraged to wear by the CDC.

Dr. Bright, are N95 respirators necessary to protect the lives of nurses, doctors, EMTs, and those on the front line?

Dr. <u>Bright.</u> Yes, they are required essential personal protective equipment to protect those frontline healthcare workers from getting infected.

Ms. <u>Castor.</u> And this is not a hypothetical concern. Just last week the L.A. Times reported a tragic story about a heroic nurse, Celia Marcos, who appears to have died because she lacked an N95 respirator when she rushed into a hospital room to try to save a COVID-19 patient who had stopped breathing.

And this brave nurse is not the only one. According to another report, over 700

staff at just one Detroit area health system have tested positive for COVID-19, and the CDC reported over a month ago that over 9,000 healthcare workers had already contracted COVID and dozens have died.

And I checked with my Tampa Bay area health providers, and one Tampa hospital said N95s are still very difficult to procure. She said there is a dire need for N95s. One of my community health centers says, we continue to struggle to get N95s.

And there are so many folks trying to sell knock-offs. And then a large Tampa Bay area health system said the supply chain remains inconsistent and irregular, and BayCare remains concerned as we head into the fall for N95 masks. The demand will continue to increase due to the flu season and the continued presence of COVID-19.

Dr. Bright, you understood that America would face a shortage of respirators in January. Is that right?

Dr. <u>Bright.</u> We understood America would face a shortage of N95 respirators for a pandemic response in 2007. And we have exercised and known and evaluated that number almost every year since 2007.

It was exercised even as late as -- early as 2019 August, in Crimson Contagion, that we would need 3.5 billion N95 respirators in our stockpile to protect our healthcare workers from a pandemic response.

Ms. <u>Castor.</u> And you sounded the alarm repeatedly but were ignored by the senior leadership at the Department of Health and Human Services. Please explain what steps that you took and the response you received.

Dr. <u>Bright.</u> We knew going into this pandemic that critical medical equipment would be in short supply. I began getting alerts from industry colleagues in mid- and early -- mid- and late January telling me that from an outside view, from the industry

view, that the supply chain was diminishing rapidly, telling me that other countries that we relied on to supply many of these masks were blocking export and stopping transfer of those masks to the United States.

I learned that China was trying to buy the equipment from the United States producers to have it shipped to China so they could make more.

And each of those alerts -- and there were dozens of these alerts -- I pushed those forward to our leadership at ASPR, to Dr. Kadlec and his senior leadership team. I pushed those warnings to our Critical Infrastructure Protection team. I pushed those warnings to our Strategic National Stockpile team who has the responsibility of procuring those medical supplies for our stockpile.

In each of those, I was met with indifference, saying they were either too busy, they didn't have a plan, they didn't know who was responsible for procuring those. In some cases, they had a sick child and would get back to it later in the week. A number of excuses but never any action.

It was weeks after my pushing that finally a survey was sent out to manufacturers or producers of those masks, a 5-page survey, asking producers or companies if they actually made those masks.

Ms. <u>Castor.</u> And in your whistleblower filing you discuss a February 7th meeting of the Department leadership group at which you urged the Department to focus on securing N95 masks. Can you describe what happened at that meeting?

Dr. <u>Bright.</u> They informed me that they did not believe there was a critical urgency to procure masks. They conducted some surveys, talked to a few hospitals and some companies, and they didn't yet see a critical shortage. And I indicated that we know there will be a critical shortage of these supplies, we need to do something to ramp

up production.

They indicated, if we notice there is a shortage, that we will simply change the CDC guidelines to better inform people who should not be wearing those masks so that would save those masks for our healthcare workers. My response was, I cannot believe you can sit and say that with a straight face. That was absurd.

Ms. <u>Castor</u>. In fact, it took 3 months from your initial warnings, until mid-April, for the Federal Government to invoke its authority under the Defense Production Act, to require the production of millions of more N95 masks. And even then the administration required the production of only 39 million masks, which is far fewer that you and other experts said that we would need.

What was a consequence of this 3-month delay and inadequate response? Were lives endangered?

Dr. <u>Bright.</u> Lives were endangered and I believe lives were lost. And not only that, we were forced to procure these supplies from other countries without the right quality standards. So even our doctors and nurses in the hospitals today are wearing N95-marked masks from other countries that are not providing the sufficient protection that a U.S. standard N95 mask would provide them. Some of those masks are only 30 percent effective. Therefore, nurses are rushing into hospitals thinking they are protected and they are not.

Ms. Castor. Thank you for your courageous efforts.

Ms. <u>Eshoo.</u> The gentlewoman's time has expired. A pleasure to recognize our colleague from Indiana, Dr. Bucshon, for his 5 minutes of questions.

Mr. <u>Bucshon.</u> Thank you, Madam Chairwoman.

And thank you, Dr. Bright, for testifying. I appreciate it.

I was a cardiovascular and thoracic surgeon and been in healthcare for over 30-some years. So I want to comment on -- I am not going to ask a question about hydroxychloroquine. I just want to comment on how the medical community responds to this type of thing.

Doctors across the country will use drugs off label in a circumstance where they don't have or they don't see a viable alternative to that, and I think this is one of those circumstances. I am hearing from doctors across the country.

And look, I am with you. You have to have double-blind studies, you have to have proof under normal circumstances. But in this situation, I think a little bit of understanding and leeway from the Federal Government is in order.

We do want to ensure the safety. This is a drug that has been proven safe for many, many years. In the appropriate doses, it does prolong the QT interval, as you have outlined, which can lead to cardiac arrhythmias if not used to properly.

But I mean to tell you, when States tried to stop doctors from using this, there was such a backlash they had to back away from it, because the physicians and the community wanted to use it.

And so doctors like me, out in the real world, if things are working, even anecdotally, they are not going to wait for the government bureaucracy to approve it. I just want to get that on the record. I am just saying, this is why doctors are using this drug. Whether it is right or not, data will show.

But, you know, if 2 years from now we have the studies, and we say, hey, that stuff really would have worked and the government stopped that from being used, if I was a family of a person that was stopped from getting hydroxychloroquine, I would be pretty mad.

I want to talk about the supply chain issues as it relates to PPE, the personal protective equipment, and I think there is enough blame to go around in the Federal Government about what happened there for -- you know, after H1N1, when our national stockpiles were depleted, we didn't replenish them. We have had people on both sides of the aisle talking about this and it is -- I think there is some -- something to -- some blame to go around.

But, you know, I don't want to be accusatory, but I do want to go over some of the facts about BARDA's situation as it relates to the masks, okay?

According to a Washington Post report, in 2015 the Obama administration and a company now known as O&M Howard -- Halyard, H-a-l-y-a-r-d, announced a project to develop rapid pandemic mask production line. According to Federal contracting records, in 2017 HHS signed off on a \$3.3 million, with an "m," payment to Halyard to build a machine that could churn out millions of protective respiratory masks at a high rate of speed during a pandemic.

However, in September of 2018 CNBC reported that the machine was never built.

And despite BARDA's \$1.5 billion, with a "b," budget, The Washington Post reported there wasn't money to pay for the project.

Why was the project scrapped, and did you sign off on that decision?

Dr. <u>Bright.</u> So that project with Halyard was to build a novel, a new machine to make respiratory protection, face masks faster, as you have described accurately.

Mr. Bucshon. Right.

Dr. <u>Bright.</u> Actually, the technical team must have reviewed that proposal on the next step or further investment in that machine. I believe that the investment to date was made to design the machine, build the blueprint for the machine, and I am not even

sure if it was to build an actual prototype of the machine.

Mr. <u>Bucshon.</u> At that time, in September 2018, were you the head of BARDA? Dr. Bright. In 2018, I was the director of BARDA.

Mr. <u>Bucshon.</u> Right. So did you sign off on the decision? Because I would expect a decision like that, a contract, money was allocated apparently from HHS to BARDA to do this, I wouldn't expect that to be scrapped without the director of BARDA signing off on that, right? So did you sign off on it? It is a yes-or-no question.

Dr. <u>Bright.</u> Not necessarily a scrapped project, sir. I don't know what the proposal was. We rely on a very thorough vetting process --

Mr. Bucshon. Understood.

Dr. <u>Bright.</u> -- through our contracting office. So that proposal to further continue that project never made it to me. So if it wasn't approved, it didn't make it through the proper vetting process in BARDA. The decision to end or continue that project was not brought to me.

Mr. <u>Bucshon</u>. Okay. I find that surprising, but I will take your word for it.

Nicole Lurie, who hired you, told The Washington Post that the Halyard contract was part of an explicit strategy to ensure we could surge mask production in the next crisis. Well, now we are here and we don't have it. So we are dealing with the consequences of that decision.

And in addition, I guess, to the Howard -- Halyard -- I keep saying that wrong -- it is my understanding -- well, I am running out of time. So what I am going to just say is, look, to doctors across America, you know, it is easy for us to sit in Washington, D.C., whether we are Members of Congress or whether we are agencies, and talk in the abstract about people dying in our intensive care units, but when you are the physician at

the bedside and there is a medication that has promise and that has a safety profile that we understand, doctors will use this medication off, you know, offline. And that is what is happening. And, you know, whether that is right or wrong, we might take years to prove, but in the meantime people can die.

I yield back.

Ms. <u>Eshoo.</u> The gentleman's time has expired. It is a pleasure to recognize the gentleman from Maryland, Mr. Sarbanes, for his 5 minutes of questions.

Mr. Sarbanes. Thank you, Madam Chair.

Dr. Bright, welcome back to this committee.

The United States Government deploys millions of dedicated public servants working together to achieve our shared goals as a Nation, to promote effective government and to protect the public interest, in this instance to protect the public health. As a scientist and public health official, that was your charge, and you took it seriously.

Unfortunately, the record shows that your superiors at HHS, and potentially beyond, instead of valuing your expertise and experience, squandered it in ways that in this moment, in the face of this crisis, amount to gross negligence. They ignored your science-based pleas to pursue critical strategies, for example, your repeated calls to obtain virus samples from China and to find supplies, masks, respirators, swabs. They dismissed your science-based warnings about pursuing unproven strategies. They dismissed your concern, for example, about the stampeding towards hydroxychloroquine. We have heard about that today.

And they sent you on errant missions to find treatments with little therapeutic value, all for the sake of satisfying political cronies. And you have testified about the

miracle cure drug that was an example of that.

Ignoring, dismissing your input, was not harmless malpractice, because there is every reason to believe that if that input had been heeded, particularly your pleas for action in the early days of the pandemic, it might have saved thousands of lives.

I want to thank you for coming forward. I want to thank you for blowing the whistle on the misguided and chaotic response to this pandemic.

I am sure there are specific conversations, emails, moments in time that you remember like they happened yesterday, the inflection points where if the response to your warnings had been heeded, things might have been different. And I am sure they haunt you and keep you up at night.

From January of this year, tell me about just one specific moment when you had that sinking feeling in the pit of your stomach because you were not seeing a response that you knew needed to happen.

Dr. <u>Bright.</u> Congressman, I will never forget the emails I received from Mike Bowen indicating that our mask supply, our N95 respirator supply, was completely decimated, and he said, we are in deep shit, the world is, and we need to act.

And I pushed that forward to the highest levels I could in HHS and got no response. From that moment, I knew that we were going to have a crisis for our healthcare workers because we were not taking action. We were already behind the ball. That was our last window of opportunity to turn on that production, to save the lives of those healthcare workers, and we didn't act.

Mr. <u>Sarbanes.</u> Thank you.

Listening to your testimony gives me chills because it all adds up to one inescapable conclusion: It didn't have to be this way. There was another path.

Things could have gone differently. The Federal response to the pandemic could have been much more effective.

So here we are at a moment when our country needs the kind of expertise and science-based guidance that you and others like you can offer us. These voices are too often being sidelined. Things are upside down. In you we have someone who made the right call in the early days and has been removed from your position, while so many people who made the wrong call still have their jobs.

Dr. Bright, when the counsel that you and others offer is cast aside -- and I know you know this -- it means that science and reason are also being cast aside. That is a dangerous impulse. It is an attitude that deprives our country in this critical moment of any real chance of getting ahead of this pandemic.

But hopefully we can learn from this. There is still time to put science and reason back into the national strategy for fighting COVID-19. We need people like you to help lead us through this.

The Federal response has got to get smarter. It has to put science ahead of politics and cronyism and wishful thinking.

Our committee will continue to press for that in the days ahead, and I know that you want to look forward. So tell us, what can we do now to learn from the mistakes of January and February and March and make sure that we navigate and lead our country through this public health crisis?

Dr. <u>Bright.</u> Congressman, we need to install and empower leadership, and we need to unleash the voices of the scientists in our public health system in the United States, so they can be heard. And their guidances need to be listened to, and we need to be able to convey that information to the American public so they have the truth about

the real risk and dire consequences of this virus, and they have the truth about the consequences of their actions if they don't follow those guidances.

And we don't have a single point of leadership right now for this response, and we don't have a master plan for this response. So those two things are absolutely critical.

I would also encourage Congress to ensure there is oversight in this response.

Large sums of funding have become available to help us, as scientists and others, respond to this outbreak, and without proper oversight of those dollars, I am concerned that they could be misdirected and lost and not put to the right fight.

So I would urge Congress to continue and increase their oversight in how those funds are being spent and making sure they are prioritized and used appropriately to end this pandemic.

Mr. <u>Sarbanes.</u> Thanks for that caution. I yield back.

Ms. <u>Eshoo.</u> The gentleman's time has expired and he yields back. A pleasure to recognize the gentlewoman from Indiana, Mrs. Brooks, for 5 minutes for her questions.

Mrs. Brooks. Thank you, Madam Chairwoman.

Dr. Bright, with all due respect, the Vice President was named the head of the coronavirus White House Task Force, which was actually a recommendation from a bipartisan blue ribbon study panel that issued recommendations years ago and thought the Office of the Vice President ought to be in charge of the response. And so, with all due respect, I believe there is that coordination.

And part of what I am very, very concerned, relative to this hearing, is that there is the impression being made that there has been no plan. And, in fact, that is part of what the reauthorization of PAHPA, that I worked closely with you, Dr. Kadlec, that Congresswoman Eshoo, Dr. Burgess, so many of us relied on you all to share with us what

we needed to do to reauthorize PAHPA, which most Members of Congress really didn't know what that was, Pandemic All-Hazards Preparedness Act. Most Members of Congress and most members of the American public didn't know we had strategic national stockpiles and that we might actually be short some of these things, until this all hit.

But we did get that reauthorized, and it was signed into law in June of 2019. Do you recall that?

Dr. Bright. Yes.

Mrs. <u>Brooks.</u> And, Dr. Bright, you joined BARDA to lead the influenza division in 2010, right after H1N1, because of your expertise, and we rely on your expertise, and you became director in 2016. After -- and you mentioned it in 2007, but after the 2009 H1N1 pandemic, the supply of masks in the Strategic National Stockpile was not resupplied. You have mentioned that actually you have had a problem since 2007.

But I have to share with you, Members like Congresswoman Eshoo and I, who have had discussions about this, many of us really didn't know that. We, as members of this committee, did not know and were not told of these shortages of masks as we worked through reauthorization of this important law.

Were you aware of this issue, and did you push HHS to maintain mask production for purposes of replenishing the Strategic National Stockpile before this happened in January?

Dr. <u>Bright.</u> Before 2017, we actually held an annual review of the Strategic National Stockpile. That was chaired by Dr. Lurie, the previous ASPR.

Since we moved the Strategic National Stockpile from the CDC management, under the ASPR management, we have not yet had an interagency, across-departmental

review of the supplies in that Strategic National Stockpile. We went through an annual prioritization process. There has always been limited funding and never enough to completely top off the stockpile.

Mrs. Brooks. Did you know Greg Burel?

Dr. Bright. I do.

Mrs. <u>Brooks.</u> He retired prior to all of this happening.

Dr. Bright. Yes.

Mrs. <u>Brooks.</u> He led the Strategic National Stockpile. Did you have conversations with Greg Burel from 2009 until 2020 about what was in the Strategic National Stockpile?

Dr. <u>Bright.</u> Absolutely. The Flu Risk Management Meeting met on a monthly basis, and each year they reviewed and prioritized items that should be purchased by the Strategic National Stockpile.

RPTR DEAN

EDTR CRYSTAL

[12:00 p.m.]

Mrs. Brooks. Okay.

Dr. <u>Bright.</u> That body -- which I actually directed for some time -- made recommendations and prioritizations to the Strategic National Stockpile. However, it was the Strategic National Stockpile's responsibility to make those purchases.

Mrs. <u>Brooks.</u> And how about PHEMCE? Does BARDA participate in PHEMCE?

And would you please -- very, very briefly, because my time is limited -- explain what

PHEMCE is? This is a plan that experts like yourselves participate in.

So I want the American people to know there have been plans, there have been plans, that PHEMCE had forth a 2017-2018 implementation plan. The White House put forth in September of 2018 a National Biodefense Plan. Did you participate in that National Biodefense Plan?

Dr. Bright. I did, and many of us did.

Mrs. <u>Brooks.</u> And it was the first time that our country had actually put forth a National Biodefense Plan. Many said it was kind of landmark, and same thing with PHEMCE putting forth many plans.

So I want the American people to know a lot of folks, over a long period of time, have been focused, but yet we did not still have enough. We didn't have enough swabs. We didn't have enough masks. We don't have enough gowns for all those incredible healthcare providers.

So I don't want everyone to be given the impression that you raised the flag just in January, okay, when you saw it was short, because you hadn't gotten the job done prior

to January. And you were at those tables, as were so many others. This happened over a very, very long period of time. And those of us have been very the disappointed to learn what was and what was not in the Strategic National Stockpile.

I thank you for your service. I thank you for your expertise. But across the board, over many administrations, we did not do enough.

And I yield back.

Ms. Eshoo. Do you want to respond, Doctor?

Dr. <u>Bright.</u> I can say that those plans have been in place, and it was disappointing they were not pulled out in January of this year and followed. They were not put on the table with a strong leader indicating these are our plans, everyone fall in line and follow through with this plan.

I can also -- I think it is important to emphasize the PHEMCE, it is the Public Health Emergency Medical Countermeasure Enterprise, which is comprised of many great scientists from across our government who put these plans in place, but since 2017 we have largely disbanded, dismantled that PHEMCE organization. We have not had those interagency discussions for a number of years, the Executive Enterprise Committee and the Executive Leadership Committee. We may have had one or two meetings at most in a new restructured or reorganized PHEMCE organization.

So the partners and colleagues across government haven't had those venues to even talk or coordinate for a number of years to understand what that plan looked like and how they would work together to implement that plan when the day came to need it.

Ms. <u>Eshoo.</u> The gentlewoman's time has expired and she has yielded back. A pleasure to recognize the gentleman from New Mexico, Mr. Lujan, for your 5 minutes of questions.

Mr. Lujan. Thank you, Madam Chair.

Dr. Bright, you have described pressure from senior Trump administration officials to promote the malaria drug chloroquine and hydroxychloroquine to treat COVID-19 despite the lack of scientific support for this treatment. According to your account, when they are offered to donate chloroquine pills to the Strategic National Stockpile on March 17, your team of experts at HHS determined that, quote, "There are safety liabilities associated with the drug," close quote, and that, quote, "Accepting the donation could lead to widespread use that is not supported by any clinical data," close quote.

Further, one of the public health experts advising you said, quote, "No data available to support that chloroquine provides clinical benefit to the treatment or prevention of COVID-19" close quote.

Yes or no, Dr. Bright, are there safety liabilities associated with chloroquine?

Dr. Bright. There are, yes.

Mr. <u>Lujan</u>. According to your whistleblower complaint, at the time of the Bayer offer the consensus from BARDA and FDA scientists was that it was advisable to wait for additional clinical data before making any recommendations on the use of chloroquine to treat COVID-19.

Is that correct, yes or not?

Dr. <u>Bright.</u> That is correct.

Mr. <u>Lujan.</u> Yet on March 19th, Bayer moved forward and announced the donation of chloroquine and President Trump told the country at a White House press conference that the drug had, quote, "shown very, very encouraging early result," close quote.

Yes or no, was the President's statement accurate?

Dr. Bright. I do not think that was the best informed statement.

Mr. <u>Lujan.</u> At that press conference the President also said had that the drug had, quote, "been around for a long time, so we know things don't go as planned. It is not going to kill anybody," close quote.

Yes or no, is that statement accurate?

Dr. <u>Bright.</u> The drug had been around a long time for its use in malaria, but it had not been around for a long time for its use in COVID-19 patients. That is a different indication, different clinical outcome, and the drug can behave differently in those people.

Mr. <u>Lujan</u>. Yes or no, is it true that within days of that press conference, you received urgent instructions from HHS general counsel, passed from the White House, directing you to obtain the authorization necessary to make the drugs widely available to the public?

Dr. Bright. That is true.

Mr. <u>Lujan.</u> Yes or no, did the pressure from the White House and HHS general counsel put you in a difficult position?

Dr. Bright. Yes.

Mr. <u>Lujan.</u> And how did you handle this pressure while still trying to protect the American people?

Dr. <u>Bright.</u> We had to come up with an alternate solution that our administration would accept.

Mr. <u>Lujan</u>. Yes or no, did the administration respect this compromise?

Dr. <u>Bright.</u> They accepted it eventually. The emergency use authorization use option was accepted by Dr. Kadlec and the administration, yes.

Mr. <u>Lujan</u>. What I am aware of, and I would agree with that, that the HHS assistant secretary for health, Admiral Brett Giroir, on April 4the said, this compromise, quote, "matters not," close, and that the drug needed to go to pharmacies, as well as hospitals.

Dr. Bright, there are only 24 hours in a day, and every hour you and your team had to spend on chloroquine is an hour you couldn't work on fighting this virus.

Yes or no, did the President's obsession with this issue distract you and others on your team from your mission of saving lives?

Dr. <u>Bright.</u> The directive we received to prioritize and put an expanded access protocol in place within 48 hours was extremely distracting to dozens of Federal scientists who were focused on the coronavirus outbreak. They had to set aside all other work to try to put together this protocol in the 48-hour directed time period.

Mr. <u>Lujan.</u> Yes or no, did it district from efforts to prepare for this crisis, including securing PPE and wrapping up testing and the production of other essential supplies?

Dr. <u>Bright.</u> It distracted from their efforts of developing other vaccines and drugs that they were focused on at that time. It was a different group of individuals who were focused on procuring PPE.

Mr. <u>Lujan.</u> Dr. Bright, just yesterday the President questioned the testimony of Dr. Fauci when discussing children and schools. The President insisted that, quote, "It has very, very little impact on young people."

Dr. Bright, yes or no, do we know that the President's statement is accurate.

Dr. <u>Bright.</u> There is a lot we don't yet know about this virus. And it is really concerning over the last few weeks that we are getting more and more data out of New

York and other places where they have had high numbers of infections of the impact of this virus in children. It is very a different presentation and outcome in children that we see in adults and it is very concerning and we don't yet have an answer for that. But we should proceed very cautiously and not have any hope or knowledge that we know everything about this virus.

Mr. <u>Lujan.</u> Dr. Bright, I want to end by quoting your testimony. Quote,
"Without clear planning and implementation of the steps that I and other experts have
outlined, 2020 will be the darkest winter in modern history."

The darkest winter in modern history.

Yes or no, do you believe this administration is doing everything it can to prevent the darkest winter? And what more should they be doing.

Dr. <u>Bright.</u> I believe there is a lot of work that we still need to do. And I think we need still -- I don't think, I know -- we need still a comprehensive plan, and everyone across the government, and everyone in America needs to know what that plan is and what role they play.

There are critical steps that we need to do to prepare for that fall, for that winter coming. We do not still have enough personal protective equipment to manage our healthcare workers and protect them from influenza and COVID-19. We still do not have the supply chains ramped up for the drugs and vaccines. And we still don't have plans in place in how we distribute those drugs and vaccines. And we still do not have a comprehensive testing strategy so Americans know which test do what, what do with that information, and we know how to find this virus and trap it and kill it. There is a lot of work we still have to do.

Mr. Lujan. Thank you, Doctor.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentleman from Oklahoma, Mr. Mullin, for his 5 minutes of questions.

Mr. Mullin. Thank you, Madam Chair. And I would be remiss not to thank you for your continued prayers for my son. That is very kind of you and I really appreciate it.

Dr. Bright. Yes.

Mr. Mullin. Where are you currently employed?

Dr. <u>Bright.</u> I am currently an employee of the Department of Health and Human Services. And I am in the middle of a transition, I guess you would say, between BARDA and NIH.

Mr. Mullin. So you have accepted the reassigned position to NIH?

Dr. <u>Bright.</u> That position is under discussion at this point. I have not yet accepted that role.

Mr. Mullin. So are you currently being paid?

Dr. Bright. I am currently being paid.

Mr. Mullin. Where are you being paid from, out of BARDA or from NIH?

Dr. Bright. It is not completely clear to me, but I believe it is out of NIH.

Mr. <u>Mullin.</u> So are you getting a paycheck since you have been -- you have been over there since mid-April, right? That is correct?

Dr. Bright. I have received one paycheck, sir. And it is my understanding --

Mr. Mullin. From NIH?

Dr. <u>Bright.</u> I think it was still part BARDA and part NIH. I have had discussions about my onboarding at NIH.

Mr. Mullin. So are you -- at BARDA you made \$285,000. Is that correct?

Dr. Bright. That is true.

Mr. Mullin. So how much are you currently making at NIH?

Dr. <u>Bright.</u> I don't think my salary has changed.

Mr. <u>Mullin.</u> It is still the same? So you have been there over there for approximately 4 weeks, a month?

Dr. <u>Bright.</u> It has been about 3 weeks since I was removed from my office at BARDA.

Mr. Mullin. So have you reported to NIH, yet.

Dr. <u>Bright.</u> I have checked in with the NIH director's office and we have discussed the onboarding process, the fingerprinting process. And we had a call just last evening to discuss the framework of my responsibilities that they have envisioned for me at NIH.

Mr. <u>Mullin.</u> So haven't actually reported to work, but you are still getting paid, correct?

Dr. <u>Bright.</u> I have been on sick leave since I was pushed out of my position at BARDA.

Mr. Mullin. Sick leave for what?

Dr. <u>Bright.</u> For very high blood pressure, and I have been under treatment from my physician.

Mr. Mullin. For hypertension?

Dr. <u>Bright.</u> For hypertension, sir, yes.

Mr. Mullin. So you are on medical leave.

Dr. <u>Bright.</u> I have been on medical leave. This week, however, I transitioned from that medical leave to annual leave so I can manage this.

Mr. Mullin. What is annual leave? What do you mean?

Dr. Bright. Vacation time.

Mr. Mullin. So you are on vacation time right now?

Dr. Bright. I am on vacation time.

Mr. <u>Mullin.</u> Did you inform your supervisors about you coming here today or did you need to do that?

Dr. <u>Bright.</u> I have informed them about my leave status. I had a conversation with them last night.

Mr. <u>Mullin.</u> So you transferred from medical leave to vacation this week or does it start next week?

Dr. <u>Bright.</u> I had a conversation with my physician about my hypertension and how we have been managing it over the last 3 weeks because this has been very stressful to be removed suddenly without explanation from my role and position. It is a life change for me. And my physician has been working very closely with me to manage my hypertension and stress. And the conversation I had with him last night indicated that --

Mr. Mullin. I guess I am kind of confused here, because you say you have hypertension, but yet you were are able to do these interviews, you are able to make the report, and you are able to prepare for this hearing. Yet, you are too sick to go into work, but you are well enough to come here, while you are still getting paid from the United States Government. Is that correct?

Dr. Bright. Sir, I have been under medical leave until --

Mr. Mullin. I get that. But if you have been on medical leave, too sick to do that, but yet you can prepare for a 2-hour hearing. I am just having a hard time tracking that. I have a hard time understanding that. And if you have hypertension and you are

too sick to go to NIH, but yet you are -- but you didn't ever experience that in BARDA, right, you never had issues in BARDA with hypertension?

Dr. <u>Bright.</u> I didn't have the level of stress of being removed from my position while I was in BARDA. So this has been very stressful. And my physician was very concerned and we have working on managing that.

Mr. Mullin. No, I get it. People handle pressure quite different. But as the director of BARDA I would feel like you are in quite a bit of a stressful position when you are trying to manage a pandemic, but you can't manage that -- or you could manage that, but you can't manage your own hypertension when it comes because you got removed from the office. But yet, you can still receive pay from NIH, but you can't show up for work. And then all of a sudden you can prepare for this, but you can't do that.

I just have a hard time understanding it. I know you are a bright individual and very smart, but you are an employee of the Federal Government. And I just want to make sure you are not doing something to deceive the American people at this time, getting paid from the United States Government.

With that, I am going to yield to Ranking Member Walden.

Mr. Walden. I thank the gentleman.

Dr. Bright, your lawyer appears to have a pretty substantial binder there. And I know Mr. Guthrie asked about the documents that are there on the table. Are those the exhibits to your complaint to the Office of Special Counsel?

Dr. Bright. I don't know what my -- I don't know --

Mr. <u>Walden.</u> I will direct it to the counsel, then, since she is answered other questions.

Are those the exhibits to the complaint to the Office of Special Counsel.

Ms. <u>Katz.</u> Some are and some are my work product and some are my notes, and they are not appropriate to turn over to Congress.

Mr. <u>Walden.</u> So is it appropriate to turn over the documents that are referenced in the complaint -- not your work product, I respect that -- to this committee? And would you do that?

Ms. <u>Katz.</u> You asked that question initially and I said we would look at the documents to determine whether they are appropriate to turn over.

Mr. <u>Walden.</u> I am just talking about the ones -- we have partial email chains, we have screen shots of emails. I think we should have the right to see those documents if we are going to effectively know the full extent of this complaint. And I just wish you would commit to turn those over.

Dr. Bright, will you turn those over?

Ms. Katz. I think I addressed that.

Mr. Walden. Dr. Bright. I am asking Dr. Bright now.

Are you willing to turn over --

Dr. <u>Bright.</u> I have submitted my full complaint to the Office of Special Counsel and that is the process I know to follow.

Mr. Walden. But you are here as an individual citizen whistleblower.

Ms. <u>Eshoo.</u> The gentleman's time has expired.

Mr. <u>Walden.</u> We just want to see what you have submitted so we can evaluate it ourselves.

Dr. <u>Bright.</u> Sir, I don't understand the full process, other than I was supposed to submit it to the Office of Special Counsel, which I have done so. I don't understand the legalities of sharing that before they have had their opportunity to review that.

Mr. <u>Walden.</u> They have certainly been shared out into the public and press.

The Washington Post has them from some source. They look a lot like what is referenced in your complaint. None of us -- I don't know where those came from. But, you know, other media outlets are certainly seeing them.

Ms. <u>Eshoo.</u> The gentleman's time has expired.

Mr. <u>Walden.</u> I just think as part of this investigation, Madam Chair, you should request them.

Ms. <u>Eshoo.</u> We will seek all information that is appropriate to be submitted to the committee. And what I circulated -- or we circulated -- to all members of the subcommittee were the emails that were public, as well as the complaint. That is what was out there.

Mr. Walden. I know, but --

Ms. <u>Eshoo.</u> I haven't tracked daily who says what. I mean, Politico has something too. I don't know the veracity of --

Mr. <u>Walden.</u> But, you know, any other investigation we would both be going we need to see all the documents as a committee. So that is all I am asking.

Ms. Katz. Madam Chair, may I address one point?

Ms. Eshoo. No. I think that we need to move on.

The gentleman from Oregon is recognized, Mr. Schrader.

Mr. Schrader. Thank you.

Thank you for being here, Dr. Bright. Really appreciate it. Tough to do. Very impressive that you are here.

Could you describe the tone and reactions of Dr. Kadlec and Dr. Azar in your January 23rd meeting when they had the all-agencies meeting on the COVID virus?

Could you describe how up to speed they seemed to be?

Dr. <u>Bright.</u> In that meeting, sir, it was one of our first meetings that we had about how to address the outbreak, and because we had practice, I came in with my list of needs and those lists for money, people, and viruses.

My request was met with a bit of surprise and puzzlement. I remember

Secretary Azar looking around the room and saying: Money, you need money? Maybe there is money somewhere. I mean, it was just something --

Mr. <u>Schrader.</u> This is despite the fact that we had had the outbreak in China for some time?

Dr. Bright. This was January 23rd at this point.

Mr. <u>Schrader.</u> Could you describe January 25th, if you remember, email exchange with Mr. Bowen on the mask situation.

Dr. <u>Bright.</u> I don't remember that specific, but I am sure it was urgent. I am sure that Mr. Bowen was sending me a notice saying -- asking if this --

Mr. <u>Schrader.</u> So you didn't ask him to come and talk to you, he just reached out to you?

Dr. Bright. Yes, sir.

Mr. <u>Schrader.</u> Okay. How about an email exchange with Dr. Kerr on January 27th? Did you reach out to Dr. Kerr? Did he come and ask --

Dr. <u>Bright.</u> Dr. Kerr reached out to me, I believe. This was because, again, he is a pandemic influenza expert as well response and he knows the vital nature of needing those viruses. And he was involved in prepping our secretary for a call he had with minister, Vice Minister Ma in China. And we knew a high priority was for our Secretary to ask for those viruses.

We have had challenges in the past of getting viruses from China from avian influenza strains and viruses. So this was a high priority because we needed that to get started. And he was alarmed when he wrote to me that morning indicating that the CDC director had reprioritized and actually indicated that we did not need to -- or he did not need to -- the Secretary did not need to ask China for viruses. And it was alarming to us because we knew how critical it was.

Mr. Schrader. That sounds incredible in light of what has transpired since then.

So I guess my major point here is that we have a brave individual coming forward as a whistleblower. But he is not alone. There are many other experts, scientists and manufacturers, that realize we were in, if I may say, deep shit, not -- a long time ago, long before the administration and the White House began to wake up.

What do you think would have happened if Mr. Navarro had not reached out to you and actually responded to you? Where would we be now if you hadn't been able to at least get one person in the White House's attention.

Dr. <u>Bright.</u> It is difficult to speculate where we were, sir. Even when Mr. Navarro reached out and strongly suggested action be taken on February 10th -- February 9th is the email, February 10th it was conveyed to Dr. Kadlec that we needed to ramp up production of N95 masks -- that order did not go out, that solicitation did not close until March 18th.

So even with the pressure of Mr. Navarro, who I think shared the sense of urgency about this outbreak, that pressure alone still did not spur Dr. Kadlec and our Strategic National Stockpile to that urgently needed action.

Mr. <u>Schrader.</u> That is very disconcerting and the reason we are here today perhaps.

Last question, if I may, switching gears and going to the other side of the spectrum. While it has been hard to get folks' attention here in Washington, D.C., in the administration on the seriousness of this, I think most people now are convinced this is a very serious issue. And I am a little concerned we are going too much the other way in terms of information.

You alluded to here on the vaccines. I think some people are under the impression there is a vaccine going to be developed in a couple of months and everything is going to be fine and I can go back to work. And, you know, we, unfortunately, have to juxtapose economic issues, they have to have realistic expectations at home. And you, I think, accurately indicated, well, it can take up to 10 years. And the quickest we did I guess was Ebola and that was, I believe, 5 years.

So it is a tough question to ask, I suppose, you don't have to answer. But to be -- I don't want America to think they can just not get back to some semblance of a new post-COVID life until a vaccine comes out, because that could take years. And there is a chance the vaccine will maybe not be as effective, much like our flu vaccines with the flu mutating year to year.

So I just want to make sure that you would -- well, I would ask you if you would agree that we can't wait to open up America up entirely until a vaccine is there, we have to use some of the other parameters you have already suggested.

Dr. <u>Bright.</u> We have to make sure that we have some scientifically led and driven decisions on how and when it is safe to reopen America. If it happens before we have a vaccine -- I mean, if we have a vaccine faster, that is great. But we do need to open America up sooner. We need to make sure everyone understands the risk, and understands the risk of their activities, and everyone has to play a critical part in following

those activities to reduce the risk.

We have to have a testing plan in place, and enough tests to make sure that we know when people are exposed so they can be quarantined and isolated and not continue to infect others.

And we are also developing a number of therapeutics that could offer some potential benefit prophylactically or protect you almost like a vaccine before you are infected. Those are being developed and maybe even faster than a vaccine. And if healthcare workers and frontline workers can use those therapeutics, that might offer them some protection as well until there is a vaccine.

So there is a number of steps in between now and a vaccine. I believe if we let science lead the discussion, and we inform America of the risk and the clear guidance on what needs to happen, and people follow that guidance, then there is a step-wise process to getting back to work and back about out of our homes.

Mr. <u>Schrader.</u> Thank you very much. I yield back.

Ms. <u>Eshoo.</u> The gentleman's time has expired and he yields back. A pleasure to recognize the gentleman from North Carolina, Mr. Hudson, for his 5 minutes of questions.

Mr. Hudson. Thank you, Madam Chair.

First let me say, I believe any whistleblower should be respected and allowed to be heard as a core component of keeping our government accountable and running smoothly. But this hearing is not about a whistleblower complaint. It is about undermining the administration during a national and global crisis, as evidenced by the fact that hearing is being held in the wrong subcommittee and well before the Office of Special Counsel finishes its work.

To disregard the minority so spectacularly in the organization of this hearing only

highlights the partisan and political nature of this hearing. I hope today will be held up in the future as a lesson of what not to do and the respect and gravity that should be given to whistleblower complaints so that they are not abused for political expediency.

More importantly, though, we have vital work we should be doing. My constituents want Congress to get back to work. So I am glad to be here to highlight the important work that needs to be done.

I heard from an ophthalmologist in my district this week about the need for relief.

She says she will consider this year a success if her practice group even breaks even.

Long story short, we should be examining the \$175 billion authorized and appropriated in a bipartisan manner for providers, and what providers still need, and recommendations for moving forward.

We should also be examining why there are gaps in outcomes and assess for minority communities. Fayetteville, North Carolina, in my district has a large and diverse community, and understandably the folks back home are scared because coronavirus hits them hardest. Why are we not spending our time today examining this crisis within a crisis more closely?

I hear from providers and hospitals about issues with PPE. I know this administration has done extraordinary things to secure more PPE. I want to thank President Donald Trump for his strong leadership. Not only did his administration moving quickly to coordinate a response, but his travel ban on January 30th was a bold move, though it was panned by his critics as an overreaction at the time.

The administration has gone to great lengths to overcome an inadequate system they inherited, and as you testified earlier, moved quickly to start programs like Project Airbridge to expedite more PPE coming in. But questions remain about why there is a

global shortage and what more Congress can do to support the administration's efforts to security sufficient PPE. This committee should be working on that question.

We have multiple pieces of bipartisan legislation waiting to be considered to improve the operations of the Strategic National Stockpile. We should be examining why our stockpile was allowed to dwindle under previous administrations.

The answers to these questions and solutions to these problems are timely and critical to helping this administration combat this virus and the deadly disease it causes.

I hear from constituents every day who are suffering under these stay-at-home orders. This crisis is hard for anyone, even if they weren't suffering from substance use disorder or mental health challenges before they were confined to their homes, and this crisis has exacerbated this problem. Why are we not examining access issues to mental health providers and the effects this crisis has had on our constituents' mental health?

Dr. Bright, you are no doubt an accomplished scientist, and I appreciate the service you have rendered this country. You deserve to be heard and your whistleblower complaints should be given the serious consideration any whistleblower complaint deserves.

But we also deserve to have the opportunity to ask questions about serious allegations that have been made against you. And I will note again, this is not the time or place for that hearing. The time is after the Office of Special Counsel has completed its work and the place is the Oversight and Investigations Committee.

But, Dr. Bright, building on questions from Mr. Walden and others, Politico released an article yesterday stating that your complaint left out a lot of information and context regarding agency decisions to require hydroxychloroquine. You chose not to elevate your concerns to the Office of Inspector General, but instead kept selective

screen shots that didn't include full context.

Another example, The Wall Street Journal reported on an email today that seems to show that you were in support of acquiring and using hydroxychloroquine.

Can you elaborate on what was missing from your screen shots and why you didn't elevate your concerns at any to the Office of Inspector General?

Dr. <u>Bright.</u> So the early days when I was aware that hydroxychloroquine, we were interested in acquiring that drug for its used in the randomized controlled clinical study. Actually, when I heard from Dr. Woodcock that it is something that we should try to investigate in a randomized controlled study, I even reached out to a company that was licensed and approved to make that drug in the United States to see if they could donate that drug to the NIH to conduct those clinical studies.

I was aware of other efforts that were ongoing to try to acquire some of that drug for its use in randomized controlled clinical studies. As long as it was going to be used at that time for those randomized controlled clinical studies, I thought we should look into the supply chain the same way I did with remdesivir.

It was only after I learned that that supply that was being discussed was coming in from Pakistan and from India, from facilities that were not approved by the FDA, and the drug was not approved for use in the United States, I became increasingly alarmed of having that drug in the United States.

Second, it was when I learned that the plan was to make that drug available through an expanded access program so people could potentially get that drug and not be under the close supervision of a healthcare provider, that caused particular concern.

It was because of that in the cascading days afterwards that we put in that emergency use authorization with the safety bumpers and barriers that we could feel

comfortable with that drug would only be used under close clinical supervision.

In the earlier days, in that email exchange that you are referring to, was before we knew about this information on Pakistan, before we knew it was going to be used for expanded access clinical -- expanded access protocol. It was when I thought our efforts to obtain some of that drug would be used at the NIH to conduct randomized controlled clinical studies. So I was relieved that we did identify some supplies of that drug for those clinical studies.

Mr. <u>Hudson</u>. My time has expired, Madam Chair. I yield back.

Ms. <u>Eshoo.</u> The gentleman yields back.

A pleasure shush to recognize the gentleman from Massachusetts, Mr. Kennedy, for his 5 minutes of questions.

Mr. <u>Kennedy.</u> Dr. Bright, thank you very much for being here and thank you for your service to our country.

Let's ground this hearing a little bit. As of this morning, which means these numbers have increased, there is nearly 1.4 million cases diagnosed of COVID-19 in the United States and over 80,000 fatalities. Experts believe both of those numbers are an undercount because after 5 months of this virus being on our shores, we have still have a systemic problem with regards to robust testing. Is that right?

Dr. <u>Bright.</u> [Nonverbal response.]

Mr. <u>Kennedy.</u> Cases in many States across the country are still actually increasing in number, despite that lack of testing. Is that right?

Dr. Bright. [Nonverbal response.]

Mr. <u>Kennedy.</u> You have mentioned in your testimony that, quote, "We missed early warning signs and forgot important pages from our pandemic playbook." Is that

right?

Dr. Bright. Yes.

Mr. <u>Kennedy.</u> Sir, you have been the head of BARDA since 2016. Is that right?

Dr. Bright. Yes.

Mr. Kennedy. Until recently.

Have you experienced any pandemics prior to this one over your course of time either there or in your prior government service?

Dr. <u>Bright.</u> We responded to the Zika outbreak, we responded to the Ebola outbreak. They didn't rise to the level of pandemic.

Mr. Kennedy. Of course. Thank you for the clarification.

Sir, you are aware at the end of the Obama administration the Obama team put together a playbook to try to guide succeeding administrations in how to handle an outbreak, correct?

Dr. Bright. Yes.

Mr. <u>Kennedy.</u> Sir, you are also aware that there was a simulation done from an outgoing Obama administration in early -- in January 2017 with an incoming administration about how to respond a pandemic. Is that right?

Dr. Bright. Yes.

Mr. <u>Kennedy.</u> And you are aware that the Trump administration cut the number of CDC staff located in China from 47 to 14. Is that right?

Dr. Bright. I don't know the exact number. I know it was reduced.

Mr. <u>Kennedy.</u> Okay. And, sir, you referenced already the simulation called Crimson Contagion. That was a simulation done by HHS begun in January 2019. Can you shed just very briefly a little bit of light as to what the findings of Crimson Contagion

were?

Dr. <u>Bright.</u> Significant findings. It was actually participants where beyond HHS, it covered broad areas of government, in Federal, State, and locals. Some of the significant findings were the need for improved coordination and communication, an alignment between the Federal, State, and local, Tribal territory governments, and the significant need for personal protective equipment, and the shortage, and the significant need funding initially.

Mr. <u>Kennedy.</u> And, sir, simulation was based off of a flu-like virus that was initially detected in China, spread by global air travel, and resulted in the infection of 110 million Americans, leading to 7.7 million hospitalized and nearly 600,000 dead. Is that right?

Dr. Bright. Yes.

Mr. <u>Kennedy.</u> Sir, when did you first have concerns about the potential impact of COVID-19 on the United States?

Dr. Bright. In early January.

Mr. <u>Kennedy.</u> And were you aware that your supervisor, Dr. Kadlec, suggested that -- the activation of the Defense Production Act in mid-January?

Dr. Bright. I wasn't aware of him are doing that. No.

Mr. <u>Kennedy.</u> Okay. You mentioned that you had two meetings with Secretary Azar, I am sure you had others, but you referenced so far in your testimony meetings on January 23rd and 27th, where you raised concerns directly to the Secretary. Is that right?

Dr. <u>Bright.</u> Yes. The Secretary was not at the second meeting. Deputy Secretary Hargan was there.

Mr. Kennedy. Thank you.

You are aware that top National Security Council staff, including National Security Advisor Mr. O'Brien and his deputy, Matthew Pottinger, raised significant warnings that China was downplaying the impacts of this virus.

Dr. Bright. I did learn of that in a meeting at the White House, yes.

Mr. <u>Kennedy.</u> You are aware that we sent 17.8 tons of medical supplies to China in early February?

Dr. Bright. I have learned of that.

Mr. <u>Kennedy.</u> Are you aware the Trump administration budget proposal released in February of 2020 called for a cut to CDC by nearly \$700 million?

Dr. Bright. I am not aware of that. I have heard of it.

Mr. <u>Kennedy.</u> Are you familiar with a memo written by Peter Navarro that warned of the impact of the virus?

Dr. Bright. Yes.

Mr. <u>Kennedy.</u> Are you aware that it was spread among senior administration and White House officials?

Dr. Bright. Yes.

Mr. <u>Kennedy.</u> Are you aware that it was on about April 2nd when the Trump administration finally activated and expanded the Defense Production Act months after being warned by you and other senior administration officials?

Dr. Bright. I have learned of that.

Mr. <u>Kennedy.</u> Are you aware that that order itself did not extend to the full authority of the DPA and left a haphazard allocation process to States and hospitals to compete against each other?

Dr. Bright. I don't know the details of that authority, sir.

Mr. <u>Kennedy.</u> Has the coronavirus Task Force actually developed a plan for reopening the country?

Dr. Bright. I am not aware of the full plan to reopen, sir.

Mr. <u>Kennedy.</u> Have they developed some principles that the White House has touted as some principles or guidelines as to how to reopen the country?

Dr. Bright. I have heard of some principles.

Mr. Kennedy. Are States following that plan?

Dr. <u>Bright.</u> It doesn't appear that there is a nationwide coordinated plan that States are following, sir.

Mr. <u>Kennedy.</u> So after this recitation of the actions and inactions of this administration over the course of the past 6 months or so, can we possibly say that this administration has prepared our country for the moment that we are in and how we could possibly be prepared for the distribution -- development, manufacturing, and distribution of a vaccine to try to address 330 million Americans over the course of the months ahead?

Dr. <u>Bright.</u> I think we have a lot of work to do to be prepared, sir, to be fully prepared.

Mr. <u>Kennedy.</u> Thank you, sir. I yield back.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentleman from Missouri, Mr. Long, for his 5 minutes of questions.

Should we go to -- you want to pass?

Okay. You can reserve and we will go to the gentleman from California, Mr. Cardenas, for his 5 minutes of questions.

Mr. <u>Cardenas.</u> Thank you, Dr. Bright, for being here today. And I just want to tell you that my family, my community, and myself, we appreciate your 25 years of focused service, specifically when it comes to addressing pandemic outbreaks. And it is my understanding that you have spent those 25 years leading teams of scientists when it comes to drugs, diagnostics, and vaccine development, and we appreciate that.

When an administration or decisionmakers prioritize politics over science, does that tend to increase or decrease the likely results of the loss of life in the middle of a pandemic?

Dr. <u>Bright.</u> I believe that scientists are best equipped to understand how to manage a public health crisis and I believe scientists should lead.

Mr. <u>Cardenas.</u> And therefore, to may question again, I will phrase it differently, if the scientists are not leading and the politicians are leading with the final decisions when trying to address the issues of pandemics that are taking people's lives, that way of handling it, does that likely increase the loss of life or it likely to increase the loss of life?

Dr. <u>Bright.</u> I believe that scientists leading will actually increase the likelihood that we can survive this pandemic and move through it. So if scientists are not allowed to lead and speak up, I believe it could increase the loss of lives.

Mr. Cardenas. Thank you.

How many times in your career have you personally activity said, "I need to enact my right to be a whistleblower"?

Dr. Bright. I am sorry, could you repeat that?

Mr. <u>Cardenas.</u> How many times in the last 25 years have you decided to enact your right to be a whistleblower?

Dr. Bright. This is my first time, sir.

Mr. <u>Cardenas.</u> Okay. I just -- I knew that answer was simple and I think I confused you because I made it so simple. And the reason why I want to say that is because I believe that you have been incredibly consistent in your willingness to dedicate yourself, your expertise, and your career to saving lives.

Is the loss of life on your mind, was that on your mind when you decided that you needed to enact your right to be a whistleblower?

Dr. <u>Bright.</u> I have spent my career focused on saving lives. And, sir, everything I have done to come forward now is to raise awareness of challenges we have, things that are not getting done, because I do think it will save more lives.

Mr. <u>Cardenas.</u> Are you aware of the fact that the lack of testing in the United States America is affected by many pieces of the puzzle in order for people to get testing, whether it is swabs, whether it is N95-rated equipment for the caregivers to be able to enact safely with the public? Are those all factors that have contributed to our lack of having adequate testing in America?

Dr. <u>Bright.</u> They are factors, sir. I don't think anyone has thought through the entire plan completely to understand those critical components for testing. I think there is a lot of confusion about the different types of tests, and I think our national narrative is focused on a number of tests, and it is not about the number so much as the right types of tests and Americans know how to use them and what to do with that information. And no one has really thought through the raw material supply chain to make sure we can sustain the need to test.

Mr. <u>Cardenas.</u> Okay. That sounds a little confusing from somebody who actually had been working at a high level of the United States Government in this space that we are discussing at this moment.

So my question is, if we are not implementing in this pandemic to the degree or ability that the United States should or could, what has contributed the most to that?

Was it the lack of scientists recommending up the chain of command or was it the people at the top of the chain of command deciding to do things differently than the scientists are strongly recommending.

Dr. <u>Bright.</u> There is evidence of scientists raising concerns about shortages and other actions that are important to take that were not being taken. It is a different level. In my personal situation as the leadership at HHS and my ASPR Dr. Kadlec that I believe was dismissive of the early warnings that I was raising.

Mr. <u>Cardenas.</u> Okay. And you said early warnings. And despite the early warnings, have there been other examples where warnings and strong recommendations were either being ignored or set aside and other actions were taken?

Dr. <u>Bright.</u> Sir, I believe that I have learned of others. I think the CDC has written several guidelines for reopening America and getting people out of their homes and back to work. I am not sure if all of those guidelines have been reviewed or are being publicly considered at this point. So there is another example of I think really hardworking career scientists and their information and their hard work not probably getting the proper vetting and proper exposure to the American public.

Mr. <u>Cardenas.</u> One of the things -- I have no idea how much time I have, because the clock has been slipping back and forth, but hopefully I have a little bit of time.

Ms. Eshoo. You are almost out of time.

Mr. <u>Cardenas.</u> We have heard boasting from the White House about millions of personal protective equipment, PPEs as everybody knows them as, millions have gone out to America. But fact, to date, we should have had billions gone out throughout America.

Isn't that the disparity?

Dr. <u>Bright.</u> It is a huge disparity. And healthcare workers are having to compromise their protection and their health and safety because they are having to be creative and reuse a single mask for the entire week or come up with novel sterilization practices that are not proven or tested yet.

So that disparity actually is impacting our frontline workers and those are the people whose lives we really need to preserve so they can treat others.

Mr. <u>Cardenas.</u> I have family members who are working in hospitals today on the front lines who have been telling me that they are wearing equipment for days at a time that they are supposed to be disposing of several times a day and are having to use them over and over.

Ms. Eshoo. The gentleman's time has expired. I thank the gentleman.

Mr. <u>Cardenas.</u> Thank you very much, Madam Chair. And if somebody could do a better job with the clock I would appreciate it. It kept flipping back and forth. I was trying to --

Ms. <u>Eshoo.</u> You are absolutely right. It went from -- it got stuck at 4:44, went to zero, and popped up to 1:21. So I am watching too. My father was a watchmaker, clock repairman. Where is daddy when we need him?

A pleasure to recognize Mr. Long from Missouri for his 5 minutes of questions.

Mr. Long. Thank you, Madam Chairwoman.

And, Dr. Bright, you contend that your removal was because the Trump administration and HHS leadership in particular lacked scientific integrity. Do you think that Dr. Fauci lacks scientific integrity?

Dr. <u>Bright.</u> Sir, I don't think my removal was anything associated with Dr. Fauci at all. I think my removal was because of tensions and actions I took between my supervisor, Dr. Kadlec, and myself.

Mr. <u>Long.</u> You know about Dr. Fauci's testimony 2 days before at the Senate HELP Committee?

Dr. <u>Bright.</u> I am aware of that testimony, yes.

Mr. <u>Long.</u> If HHS leadership is so hostile to scientific integrity as you say, as you allege, how do you explain Dr. Fauci being allowed to testify forthrightly, to serve in a prominent role on the White House task force, the administration, and direct NIAID's extensive research efforts?

Dr. <u>Bright.</u> Sir, I am not sure what decisions are involved in allowing Dr. Fauci to testify or not. That is not something --

Mr. Long. Can you say that again? I am having --

Dr. <u>Bright.</u> I am not sure -- I am not aware of what process or decisions are involved in allowing Dr. Fauci to testify or not.

Mr. Long. But he was allowed to testify.

Dr. <u>Bright.</u> I know he was, but I thought I understood you to ask me if that was appropriate or if he was not being allowed to. Maybe you can repeat your question if I misunderstood it.

Mr. <u>Long.</u> Okay. What I am saying is you are saying HHS is hostile to scientific integrity. And if that is the case, can you explain why Dr. Fauci was allowed to testify forthrightly in the committee? If they are hostile, why would you let him come out and testify without any -- no holds barred?

Dr. Bright. I am saying that my supervisor was not following proper scientific

process that we have in place for BARDA. I am not actually saying the administration is hostile against scientific integrity in all cases. So I am saying in my particular situation, as in my claim, my supervisor was conducting inappropriate activity that was going around proper scientific vetting. That is what I put in --

Mr. <u>Long.</u> Why did you not bring these concerns to Secretary Azar, or his chief, or the inspector general? Why did you not bring any of them into the loop and say, "Hey, I have these concerns"?

Dr. <u>Bright.</u> Sir, I believe some of the activities were not -- it is isolated with Dr. Kadlec. I think some of his senior staff was also aware of some of the processes that were being utilized to go around our traditional review process, scientific review process.

Mr. <u>Long.</u> But wouldn't normal protocol in any situation be that you go to the Secretary at HHS, or his chief of staff, or the inspector general with your concern, instead of just gathering them up and deciding that one day you are going to --

Dr. <u>Bright.</u> Well, I didn't decide that. I was pushed out, sir, and involuntarily transferred, without my knowledge.

Mr. <u>Long.</u> But you had these concerns. So why didn't you take them to your superiors when you had the concerns and maybe none of this -- maybe we wouldn't be here today? It wasn't easy for any of us to be here today.

Dr. <u>Bright.</u> Sir, I requested an IG investigation, as in my claim, I think it was in 2018, that they look into what I believe was inappropriate pressure, political pressure on some of our contracting activities and discussion about procurement integrity. And I do not think that that was ever followed through on. So --

Mr. Long. Did you bring your concerns to the inspector general?

Dr. Bright. I do not believe they were followed through and submitted to the

inspector general. I raised those concerns to our HHS --

Mr. <u>Long.</u> But you personally didn't talk to the inspector general, didn't raise concerns with the inspector general --

Dr. Bright. I did not.

Mr. Long. -- or with Azar's chief or with Azar, correct?

Dr. <u>Bright.</u> I raised those with the Secretary's Office of General Counsel, they were present in the meeting, sir.

Mr. Long. I will take that as a no. Okay.

You state in your testimony that HHS leadership was dismissive about your predictions about the broader outbreak and the pressing need to act. However, it is my understanding that it was Dr. Redfield at CDC who alerted the White House's National Security Council about the risk of the virus on January the 2nd and a high level team with the NSC's Counterproliferation and Biodefense Directorate quickly began meeting to address the possibility of a pandemic. Do you consider Dr. Redfield's actions here to be dismissive about the threat of a coronavirus?

Dr. <u>Bright.</u> Sir, people were aware of the urgency. What was lacking was the action and how to address the urgency. So when we were raising issues on critical supply chain of medical equipment to protect doctors and nurses, if they are aware the urgency of the situation and still failed to act, I think that is even more unconscionable than not being aware of the emergency and not acting.

Mr. <u>Long.</u> In your new position I would recommend that if you have issues, you might go to the head of the department, his chief, and some folks like that.

I yield back.

Ms. Eshoo. The gentleman yields back. A pleasure to yield to the gentleman

from Vermont, Mr. Welch.

Mr. Welch. Thank you very much.

Your job, our job is to protect the American people. And this fierce virus can be managed if done correctly, correct?

Dr. Bright. I believe so.

Mr. <u>Welch.</u> And in fact the playbook is established. It is testing, contact tracing, and then isolation, starting with first social isolation, correct?

Dr. <u>Bright.</u> Yes. Those nonpharmaceutical interventions and testing are critical first steps.

Mr. <u>Welch.</u> Right. And in fact this virus is across the world, and many countries that have followed that tried and true protocol have done far better than the U.S. Is that correct?

Dr. <u>Bright.</u> We have seen differences in the response and the outcomes of that response around the world.

Mr. <u>Welch.</u> I will go through some of those. You know, the Johns Hopkins study that said that the U.S. had the best preparedness, it turned out we have the worst response, correct, with the most cases and the most deaths?

Dr. Bright. We had the most cases and the most deaths.

Mr. <u>Welch.</u> And I did some calculations. On January 19th, South Korea determined its first case. On January 19th, the U.S. determine its first case, correct?

Dr. Bright. January 20th was the U.S. case, yes.

Mr. <u>Welch.</u> And if we have the same response in South Korea by population, they had 33,000 deaths, we would have saved 50,000 lives.

In Taiwan they had the same virus, 22,000 deaths. And again, adjusting for

population, that is 60,000 more deaths we have had here. Singapore, 82,000 more deaths. New Zealand, 65,000.

The question for us here, and for the American people, is, why, when we had the best plan, we had the worst execution?

So let me go through a few things that you have established. One, beginning in January, before that case here, FDA chief Hahn asked the HHS if he could start contacting companies about possible shortages of protective equipment and he got blown off by HHS, correct?

Dr. Bright. What I understand.

Mr. <u>Welch.</u> And on January 18th, before our first case, you pushed Dr. Kadlec to convene high-level meetings about the virus but that was initially rejected, correct?

Dr. Bright. True.

Mr. <u>Welch.</u> And then On January 23rd you demanded urgent access to funding personnel and clinical specimens to develop lifesaving medicines, but you were told that the spread was under control, correct?

Dr. <u>Bright.</u> There wasn't a shared sense of urgency.

Mr. <u>Welch.</u> On January 25th you warned others in the administration there is a critical need for procuring surgical masks. That was ignored, correct?

Dr. Bright. True.

Mr. <u>Welch.</u> On January 27th you participated in the daily COVID-19 meeting where you expressed frustration with the slow pace of accessing virus samples and clinical specimens from China. You were reprimanded and you were no longer part of those meetings. Is that right?

Dr. Bright. That is true.

Mr. <u>Welch.</u> So you and others actually were seeing over the horizon what was coming to our shores, even before our first case was confirmed, correct?

Dr. <u>Bright.</u> We had spent many years preparing for a pandemic, sir. And we understood the threat, we understood what we needed to do.

Mr. <u>Welch.</u> Exactly. It is knowable and it is manageable. It is fierce and fearsome. But what you have to do is established. Is that more or less correct?

Dr. Bright. Yes, sir.

Mr. Welch. We just didn't do it.

February 25th, President Trump gave an assurance that the stock market is starting to look very good and the coronavirus was very much under control. Were you aware of any medically involved people who had the view that the virus at that time was very much under control?

Dr. <u>Bright.</u> No, sir. I don't think the virus was under control. I don't think many people would agree with me in the scientific realm.

Mr. <u>Welch.</u> Now, in those countries I mentioned, that includes Germany,

Taiwan, New Zealand, South Korea, Singapore, the leaders of those countries accepted
that there was a role only the nation could play and the provinces would have to depend
on them for that. And I want to go through some of those things.

One, establishing a testing protocol. Was that done here.

Ms. Bright. No.

Mr. <u>Welch.</u> Two, acquiring and allocating and distributing the personal protective equipment to where it was needed when it was needed. Was that done here?

Dr. Bright. No, sir.

Mr. <u>Welch.</u> In fact, we had governors and hospitals competing with each other to try to get desperately needed equipment. Isn't that correct?

Dr. <u>Bright.</u> There was a lot of confusion, and a lot of competition, and bad decisions made to acquire poor quality product.

Mr. <u>Welch.</u> In any of those other countries that I just mentioned, are you aware of the leader of that country at a press conference making recommendations on what kind of medication people should use?

Dr. <u>Bright.</u> I don't know the details of what happened in those countries, sir, so I don't know.

Mr. <u>Welch.</u> All right. We had governors here, Republicans and Democrats, Republicans like Hogan, like Phil Scott from Vermont, who have done a tremendous job, but no matter how good they do their job, can they protect their people without the aggressive intervention of the Federal Government playing its role?

Dr. <u>Bright.</u> I think the Federal Government plays a critical role in coordinating and aligning and making an equitable distribution of those critical supplies. I believe that is what we practice and exercised in the past that there would be a critical role for the Federal lead in coordination at the State, local, and Tribal and territorial levels.

Mr. Welch. Thank you Dr. Bright.

I yield back.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentleman from Georgia, Mr. Carter. Do you wish to question or do you want to pass?

Mr. Carter. I will reserve.

Ms. Eshoo. You reserve. Okay.

The gentleman from California, Mr. Ruiz, is recognized for 5 minutes of questions.

Dr. Ruiz.

Mr. Ruiz. Thank you.

Thank you, Dr. Bright. Thank you for your testimony here and thank you for your service to our country.

My heart aches for the family and friends of the over 80,000 in America who have died of COVID-19 in such a short period of time. In fact, my heart aches for those closer to me. Riverside County has reported 228 deaths.

As a doctor, I appreciate your written testimony that states that science, not politics or cronyism, must lead the way to combat this deadly virus. There has been a lot of hype about cures for COVID that have been shown to be ineffective and even dangerous. We are now seeing the very real dangers and consequences of not making decisions based on science. Hydroxychloroquine, which FOX News commentators and then the White House repeatedly touted and actually encouraged people to use, is Exhibit A on this list.

But there is one drug that appears to provide some therapeutic benefit, remdesivir. Two weeks ago, Dr. Fauci announced that remdesivir showed a clear-cut, significant, positive effect in diminishing the time to recovery.

My understanding is that in January and early February you launched a comprehensive review to assess which existing drugs may prove a therapeutic benefit and you quickly identified remdesivir as the most likely drug to be effective against COVID-19. Can you describe how you came to that conclusion, who you told within HHS and what the response was?

Dr. <u>Bright.</u> Yes, sir. That conclusion came about by a technical review from a number of scientists within HHS, the CDC, FDA, NIH, and BARDA. It was also aligned

with a scientific assessment from WHO and a number of global experts who rapidly looked at every potential drug and ranked remdesivir as the drug that had the most potential for benefit.

Mr. Ruiz. Who did you tell and what was their response?

Dr. <u>Bright.</u> We shared that information with Dr. Kadlec. We shared that information within HHS leadership as well. We had discussions about the actions that could be considered for acquiring the limited supply of remdesivir.

Mr. Ruiz. What was the response?

Dr. <u>Bright.</u> We had discussions about how to ramp up production of more remdesivir in case the randomized controlled clinical study that the NIH was conducting came through with positive --

Mr. <u>Ruiz.</u> So you had a discussion and what was the response? Did anything happen?

Dr. Bright. No decision was made at that time.

Mr. <u>Ruiz.</u> Okay. My understand is that Peter Navarro, the White House trade advisor, reached out to you on February 7th to seek your counsel. You told them about your top three concerns, the shortage of N95 masks, the need for a, quote, unquote, Manhattan Project to develop vaccines, and securing adequate supplies of remdesivir. Can you tell us if Mr. Navarro agreed with you and what steps you and he took?

Dr. <u>Bright.</u> Mr. Navarro did agree with me on the remdesivir, the N95 masks, and the vaccine Manhattan Project, and he drafted a memo on February 9th to the White House chief of staff and Mick Mulvaney to share with the White House task force.

Mr. <u>Ruiz.</u> The directive for HHS to act on remdesivir occurred on February 10th.

What happened next? And did the Department promptly procure the needed supplies

of remdesivir?

Dr. Bright. We did not proceed with procuring any supplies of remdesivir.

Mr. <u>Ruiz.</u> Okay. You were removed from your position on April 22nd. By the time you were removed, had the Department settled on a plan and procured the remdesivir?

Dr. <u>Bright.</u> No, sir. They were still discussing with slide presentations about potential donations of remdesivir at that time.

Mr. <u>Ruiz.</u> So what you are describing is a gang that couldn't shoot straight. And yet, we are in the middle of a pandemic. There is one drug the experts say could make a difference and in fact has been shown to make a difference. Yet, the Department can't seem to figure out how to acquire it.

A week ago The Washington Post published an article on the rollout of remdesivir, describing it as, quote, "confusing, unfair, and marred with incomplete medical information," unquote. Doctors described how they can obtain the drug and don't understand the process for accessing it. Dr. Benjamin Linas from the Boston Medical Center said, quote, "There is no transparency. The process is just a staggering injustice."

Dr. Bright, you were warning about this over 3 months ago. If the Department had listened to you and the other experts at your agency, could this fiasco have been avoided?

Dr. <u>Bright.</u> We would have had a plan, sir. We should have had a plan for that drug and any other drug in limited supply.

Mr. Ruiz. So it didn't have to be this way.

Dr. Bright. Right.

Mr. Ruiz. Here is what I don't understand. You were right about the dangers of

hydroxychloroquine, you were right about the benefits of remdesivir, you were right about N95 masks and other critical issues, yet you got fired from your job, while officials who botched the response and ignored your warnings stay in theirs. Not only is this unfair to you, it is completely dangerous to the American people.

I yield back my time.

RPTR MOLNAR

EDTR ROSEN

[1:00 p.m.]

Ms. <u>Eshoo.</u> The gentleman yields back. I would like to clarify something just very quickly. Relative to your leave, Dr. Bright, are you on accrued vacation time now?

Dr. Bright. I am sorry?

Ms. Eshoo. Are you on accrued vacation time now?

Dr. Bright. I am on approved vacation leave today, yes. I talked to the --

Ms. <u>Eshoo.</u> And would you be willing to share the exhibits once you personally -- once you remove personally identifiable information?

Dr. <u>Bright.</u> Congresswoman, I am having trouble understanding you through the mask.

Ms. <u>Eshoo.</u> Oh, I am sorry.

Dr. Bright. Sorry.

Ms. <u>Eshoo.</u> I am getting so comfortable wearing a mask, I forgot I had it on. Would you be willing to share the other exhibits once you remove personally identifiable information?

Dr. Bright. Yes.

Ms. <u>Eshoo.</u> Thank you. All right.

Ms. <u>Katz.</u> Chairwoman, we will make them available after the hearing today when we have had a chance to review it.

Ms. <u>Eshoo.</u> Thank you.

Mr. <u>Walden.</u> Madam Chair, will they be made available to the minority as well as the majority?

Ms. Katz. Absolutely.

Ms. <u>Eshoo</u>. They will be made available to the entire committee.

Mr. Walden. Perfect. Thank you.

Ms. <u>Katz.</u> We have never shared anything with the majority that hasn't been shared --

Ms. Eshoo. Right.

Ms. Katz. -- this is a bipartisan issue.

Mr. Walden. Thank you.

Mr. <u>Griffith.</u> Madam Chair, if there is anything in those exhibits that hasn't already been released to the public that might be degrading, will that be kept in confidence amongst committee members?

Ms. <u>Eshoo.</u> I am sorry. I didn't hear you.

Mr. <u>Griffith.</u> Not knowing what is in the emails, I am wondering if there is any information in there that might be deemed to be degrading, would that be kept in confidence amongst the committee members as opposed to being released to the public?

Ms. Eshoo. We will follow the rules.

Mr. Griffith. And that is in compliance with rule 11. Thank you.

Ms. Eshoo. Thank you, sir.

Okay. I now have the pleasure of recognizing the only pharmacist in the United States Congress, Mr. Carter.

Mr. Carter. Thank you, Madam Chair.

Thank you, Dr. Bright, for being here, and thank you for your service to our country. And before I begin, let me extend my condolences to those 80,000-plus who have lost their lives and to their families as a result of this pandemic, and a shout-out to

all of our healthcare professionals as well as our other essential workers who have put their own health in danger in order to provide services to our citizens.

Dr. Bright, it is my understanding that in 2017, BARDA funded a project with Applied Research Associates of Albuquerque to develop respirators that could be sanitized and reused during public health emergencies, such as what we are going through today. However, according to recent reports by The Washington Post, none of these next generation respirators are available for us today. Why is that? Do you have any idea?

Dr. <u>Bright.</u> I am not aware of those. Are you talking about the ventilator, sir, that we developed?

Mr. <u>Carter.</u> That is correct. I am talking about those that were developed, the respirators that were developed and could be sanitized and reused during public health emergencies. It is my understanding that that was contracted and that that project was scrapped.

Dr. Bright. Sir, I am not familiar with that project to resanitize the respirators.

Mr. <u>Carter.</u> You are not familiar with that project, and you didn't sign off on that project, to your knowledge?

Dr. Bright. I am not familiar with that project to resanitize respirators.

Mr. <u>Carter.</u> Okay. Fair enough if you are not familiar with it.

Let me ask you this: We have had a lot of discussion today about hydroxychloroquine, about chloroquine, and I am a little bit confused here because it is my understanding that this is what BARDA -- do you want to clarify something here? I see you -- okay. It is my understanding that that is what the role of BARDA, the mission of BARDA is, to look at things like this, in fact, when we in Congress appropriate, allocate

money to go toward this, that you are supposed to be looking -- that BARDA is supposed to be looking at things that could possibly have merit, such as hydroxychloroquine and chloroquine. And early on, it appeared that you embraced that.

And early on, it seemed that you were in favor of looking at that. And I am just wondering because of this pandemic, because we didn't have any vaccine or any kind of agreed-upon treatment, we should be testing, and we should -- that is what we are appropriating that money for. Would you agree with that, that that is what we are trying to do is to look at what could possibly work, and work with public companies to try to encourage them to come up with those kind of solutions?

Dr. <u>Bright.</u> Absolutely. We should look at all options and make sure we evaluate the potential risk and safety and benefit of those in the context of a randomized controlled clinical study. In the context of emergency, we should move swiftly and get that clinical data as urgently and quickly as possible, that we should not proceed recklessly without that clinical data on its potential adverse events in an emergency.

Mr. <u>Carter.</u> So you are referring -- when you say, we should not proceed adversely, you are referring to hydroxychloroquine and the chloroquine?

Dr. <u>Bright.</u> We are -- we were promoting the standing up of randomized controlled clinical studies at the NIH with hydroxychloroquine. I worked with a company to even ask if they would donate drug to the NIH to be used in the context of a randomized controlled clinical study.

Mr. Carter. Right.

Dr. Bright. Yeah. So that is what BARDA would do.

Mr. <u>Carter.</u> And, in fact, I think you worked with the FDA to get an emergency use for hydroxychloroquine. Is that correct? And it was actually approved by the FDA.

Dr. <u>Bright.</u> That was in the context of the directive we received from the Secretary's office to stand up an expanded access protocol. Our clinicians --

Mr. <u>Carter.</u> So are you saying you were instructed to do that, and you did it against your will, or --

Dr. <u>Bright.</u> Sir, we were instructed to put in place an expanded access protocol. So in the context that Americans be able to access this drug and not be under the close supervision of a physician. The scientists at FDA, NIH, CDC, and BARDA worked together to change that directive to the context of emergency use authorization with guardrails in there so patients would be under the close supervision of a physician.

Mr. <u>Carter.</u> Understood. Let me ask you this: Initially, you appeared to be encouraged by what could possibly be a result of the effect of hydroxychloroquine. When did that change? When did you sour, if you will, on the use of hydroxychloroquine?

Dr. <u>Bright.</u> I believe that we have seen many drugs that could have benefit, and some of these are really interesting things we have never heard of, some we have.

Mr. <u>Carter.</u> I understand that, but my question was, when did you sour on it?

Dr. <u>Bright.</u> When it was determined that this drug should be made available to Americans outside the context of a close physician supervision. So I supported conducting a randomized controlled clinical study for hydroxychloroquine at the NIH. When I learned that there was a directive to make it more broadly available, not under close supervision of a physician, I was --

Mr. <u>Carter.</u> When was that? When did that directive go out?

Dr. Bright. That was March 23rd.

Mr. Carter. March -- and that is the time that you decided, no, this is not what

we should do, and we should not be looking at hydroxychloroquine at all?

Dr. <u>Bright.</u> I didn't think that was the proper, safe way to evaluate that drug in the context of this outbreak. I believe it should be only done under close supervision of a physician. When we put the EUA in place that locked this drug down, to only be used in patients under close supervision of a physician, we were satisfied we had those guardrails in place. When an email string followed a week later saying ignore the EUA, push this drug into the retail pharmacies in New York and New Jersey, that is when I became more concerned.

Mr. <u>Carter.</u> And who put that directive out?

Ms. <u>Eshoo.</u> The gentleman's time is expired.

Mr. <u>Carter.</u> Who put that directive out?

Ms. Eshoo. The gentleman's time is expired. You can answer, Dr. Bright.

Dr. Bright. Which directive, sir?

Mr. <u>Carter.</u> That it should be put out to the public without physicians approving it.

Dr. <u>Bright.</u> That directive was an email string that had a number of individuals on it, and I believe it first came from Dr. Giroir, the Assistant Secretary of Health, that indicated the White House was asking for that drug to be more broadly available.

Mr. <u>Carter.</u> So was it because the President was encouraged by the use of this drug that you became discouraged by it?

Dr. <u>Bright.</u> It had nothing to do with politics, sir. I wanted to make sure that Americans were aware of the risk of this drug. It was only available under very --

Mr. <u>Carter</u>. But it is a drug that is indicated and has been used safely in the past.

Ms. Eshoo. The gentleman's time has been exceeded by almost --

Dr. Bright. In one area.

Ms. <u>Eshoo.</u> -- one-and-a-half minutes.

You can finish your answer, Dr. Bright, and then we are going to move to the next member.

Dr. <u>Bright.</u> The drug had been used safely for malaria for a number of years. We didn't have a database --

Mr. <u>Carter.</u> But it is being used in the same dosage as it is for malaria.

Ms. <u>Eshoo.</u> The gentleman's time is -- please, please. I know that I am overly generous with both sides of the aisle, but I think that we need to move on. I mean, 2 minutes of extra time is 2 minutes of extra time, and I am not going to ask that it be shared over here. The gentleman's time is expired.

It is a pleasure to recognize the gentlewoman from Michigan, Mrs. Dingell, for her 5 minutes of questions.

Mrs. <u>Dingell.</u> Thank you, Madam Chair. Thank you to both you and Ranking Member Dr. Burgess, and Dr. Bright, for your being here today. You are doing a great service.

I think we are here today because COVID is real. I share the sentiments of many of my Republican colleagues that have expressed the thanks to the frontline workers asking questions. I want to look at the last few months. COVID's really real in my State. Michigan's the 10th largest State in the country, and we were third in the number of cases for weeks. We were third and remained there until this week in the number of deaths. We managed to move to fourth place 2 days ago, which is not a number anybody wants to be. My family alone, a cousin woke up with 104 temperature and was dead that afternoon.

There are people still dying every single day. I have lost someone I have known. Sunday, Monday, a brother, a brother-like friend to me, Tuesday and Wednesday. And then we hear the scientific experts, yourself, but Dr. Fauci, other scientists around the country saying to us, if we don't listen to them, we could begin to see -- we are going to see a return. You call it a dark winter. I call it, I don't want to see any more spikes. I don't want to see anybody else die. I am losing too many friends that I know, and people across the country are.

So I want to focus on an area that is not your area of expertise, but it is mine, car safety. We expect our cars to be safe. And we expect car manufacturers to be responsible and making sure defective cars aren't sold. And if they fail in that responsibility, we hold them accountable. If an engineer in a car company realized a model had serious defects and warned her management about that, we would all think she had done her job responsibly. And if management ignored her, and our committee found out, I will bet you right now, we would be having hearings. And if Americans died driving those cars, the companies would be sued, and they would be charged with criminal negligence.

In fact, several years ago, before my time, this committee investigated airbag defects and vehicle safety. At the time, the subcommittee's ranking member, Dr. Burgess, said, there is no room for going slow when it comes to safety. And certainly deception cannot and will not be tolerated. Dr. Burgess was right then, and our car makers have to be accountable. But what I am concerned about is that we aren't applying these same standards to coronavirus. And I want to learn from what has happened, so we keep that dark winter you are talking about from happening.

It seems to me, Dr. Bright, you acted the same way the auto engineer I mentioned

should act. You identified serious problems, and then suggested fixes when it came to diagnostics, N95 masks, other equipment, and medicines. Is that right?

Dr. Bright. That is true, and, Congresswoman, we still have those challenges.

Mrs. <u>Dingell.</u> Do you believe if your suggestions were implemented, lives would have been saved, and the severity of the pandemic might have been lessened?

Dr. <u>Bright.</u> I believe lives would have been saved if we had proper medical protective equipment for our healthcare workers, yes.

Mrs. <u>Dingell.</u> So people died because you weren't listened to?

Dr. <u>Bright.</u> People died because they didn't have appropriate protective equipment to save their lives and protect them from getting infected.

Mrs. <u>Dingell.</u> The problems aren't limited to just ignoring your advice. The American people are confused, given mixed signals, and quite frankly, some days just simply deceived. Let me give you an example. There was a visit to the CDC on March 6, and at that visit, the administration said, anybody who wants a test will get a test. Was that true then?

Dr. <u>Bright.</u> There still are not enough tests.

Mrs. <u>Dingell.</u> So even this week as we are being told, anybody who wants a test can have a test. Is that true in the United States of America?

Dr. Bright. No.

Mrs. <u>Dingell.</u> In fact, all the experts say we are doing is only a small fraction of the tests we need to do to reopen safely. I am running out of time, so let me ask you about vaccines. We keep being told by the White House that we have heard very soon, quick numbers, a matter of months for that vaccine to be developed. This is your area of expertise. You are a top immunologist in the world. Was there any scientific basis

to suggest in March that we will have a vaccine in the next few months?

Dr. <u>Bright.</u> There is a lot of optimism, there is a lot of hope, but that doesn't make a vaccine. There is a lot of work that needs to be done to make a vaccine.

Mrs. <u>Dingell.</u> Will we be able to vaccinate people in the next few months? Dr. Bright. It is very unlikely.

Mrs. <u>Dingell.</u> Thank you, Doctor.

Ms. <u>Eshoo.</u> The gentlewoman yields back. It is my understanding the minority is passing, reserving. So with pleasure, I recognize the gentlewoman from New Hampshire, Ms. Kuster.

Ms. <u>Kuster.</u> Thank you, Dr. Bright, for being with us today. I want to thank you for your courage, for helping us to do our job to protect the American people.

I want to start today by restating what I said at a hearing February 26th with Secretary Azar, right here, right at that table. The key to a public health crisis is trust and credibility. On that day, I urged Secretary Azar to provide clear, credible updates from this administration to the American public. However, your whistleblower complaint and testimony today unveil unheeded warnings about personal protective equipment, testing supplies, and vaccine supplies.

Over the past several months, I have held countless conversations with doctors and nurses and hospitals and community health centers and our Republican Governor and every other person in New Hampshire, trying to get access to personal protective equipment, to protect our frontline workers, to protect our grocery clerks.

We have been trying to get testing supplies, and we were told that because we were not a hotspot, we were on our own. And we literally had to turn to entrepreneurs. Thank God they exist, and thank you to them for flying to China and bringing us the

equipment we need that should and could have been distributed, had we planned ahead.

These conversations have informed my roadmap to recovery on how to safely reopen our economy, and key to those efforts is adequate testing, contact tracing, supported isolation, and vaccine development -- your specialty. So I want to focus on your role as Director of BARDA in vaccine development and distribution.

On page 28 and 29 of your addendum to your complaint, it states that BARDA estimated that between 650 million and 850 million needles and syringes would be needed for a vaccine to be administered here in the United States for everyone to be safe. Your team at BARDA also estimates it could take up to 2 years to manufacture these vaccine delivery supplies.

To your knowledge, Dr. Bright, at this time, has the administration placed any orders to prepare for how a vaccine will be delivered when one becomes available to every American?

Dr. <u>Bright.</u> I learned that they placed an order, the first order for needles and syringes on May 1st, and another order was placed today.

Ms. <u>Kuster.</u> And were the amounts adequate?

Dr. Bright. I believe it is for 320 million needles and syringes.

Ms. <u>Kuster.</u> And could you please describe the situation if every American does not have access to the vaccine due to a supply shortage?

Dr. <u>Bright.</u> That situation would be catastrophic, honestly. The decisions have not been made yet who to vaccinate first, how to identify those individuals, and how to stretch those limited supplies appropriately. And it is important to remember --

Ms. <u>Kuster.</u> Let me ask you a simple question.

Dr. Bright. -- that it is not just the United States, so there is has limited supplies.

When I said it would take 2 to 2-1/2 years to make those, that was assuming there wouldn't be global competition for those limited supplies. Those are not made in the United States, some of them, so --

Ms. <u>Kuster.</u> Does a lack of preparation in vaccine supplies make us more vulnerable to future spikes in COVID-19?

Dr. Bright. Absolutely.

Ms. <u>Kuster.</u> And do we have enough supplies to distribute both the flu vaccine next winter as well as the coronavirus vaccine?

Dr. <u>Bright.</u> It is going to be extremely challenging.

Ms. <u>Kuster.</u> Do we know yet of the interactions of the full-fledged flu season in combination with COVID-19?

Dr. <u>Bright.</u> We haven't seen that yet. Luckily in this spring, flu was winding down when COVID-19 was emerging.

Ms. <u>Kuster.</u> And without adequate supplies to vaccinate all Americans for COVID-19, does this slow down the goal of fully reopening our economy, and getting back to the normal that every American wants?

Dr. <u>Bright.</u> It certainly brings caution and significant consideration that must be taken into consideration before re-opening. We need to make sure that not only the guidelines for reopening are clear to each individual, and each individual follows those guidelines. Otherwise, it puts us all at risk.

Ms. <u>Kuster.</u> So can I ask you a question, and I know you are not political, and certainly, we are all trying not to be political. In fact, I am very proud in our State that our delegation and our governor are working so well together. But Dr. Bright, does this virus give a damn whether a patient is Republican or Democrat?

Dr. <u>Bright.</u> No, it doesn't. This virus just wants to infect people, and unfortunately, a lot of those people get really sick, and many of them die.

Ms. <u>Kuster.</u> Thank you. I am so grateful, not just for your knowledge, for your humility, and for your service to our country. Thank you, and I yield back.

Dr. Bright. Thank you.

Ms. Eshoo. The gentlewoman yields back. Minority reserves?

Pleasure to call on the gentlewoman from Illinois, Ms. Kelly, for her 5 minutes of question.

Ms. <u>Kelly.</u> Thank you so much, and thank you for being here and your patience. As chair of the Congressional Black Caucus Health Brain Trust, I am deeply concerned by the disparities that this pandemic has brought to light due to our Nation's history of discriminatory policies, leading to differences in health outcomes for people of color. Time and time again, when resources are scarce, some communities are forced to do without the goods and services they need. You identify multiple situations in which the United States would face a shortage of supplies needed to respond to COVID-19, from masks to swabs and other testing materials, and potentially, the supplies that deliver a vaccine when one is ready.

During COVID-19, we have seen some States forced to pay significantly more because they are on their own to procure those medical supplies. Not every State or locality can afford to do this. Knowing what we do know about how scarce resources are procured and distributed, what impact will shortages have on lower-income communities?

Dr. <u>Bright.</u> The syringes will impact across all of America, and unfortunately, it actually increases the concern in communities that aren't part of the mainstream and

might have lower socioeconomic status. So I think it has a significant chance of increasing the risk in those communities.

Ms. <u>Kelly.</u> How have you seen this impact the devastation of the disease in these communities?

Dr. <u>Bright.</u> In these communities, the data are showing that they are hit very hard, and we don't actually have the information yet to understand fully what is behind that or why, and health status or access to healthcare or other immunization status or healthcare status. So, we are still learning a lot about that.

However, it is really important to think about when we have diagnostic tests and other things available, that they are available to everyone. And many of these tests that we are developing today are very expensive, or are in very rare supply. So we need to make sure that we are developing and making available tests that are not just rapid and accurate, but low cost, and so everyone who needs a test can access those tests.

Ms. <u>Kelly.</u> Did you attempt to urge HHS leadership or the administration to consider preparedness, outreach, or targeted resources for these populations, or are you aware of any HHS administration actions to target resources outreach to these vulnerable groups?

Dr. <u>Bright.</u> I am -- I have had some conversation. There have been some conversations, I should say, focusing on groups that are harder to reach and in different socioeconomic status. I am not sure that there is a solidified plan in place just yet to make sure that it is more than a conversation.

Ms. <u>Kelly.</u> Doesn't sound like there is. In your testimony, you recommend establishing a national standard and coordinate equitable distribution of equipment and supplies. Will this help to ensure that every community can access the equipment and

supplies they need?

Dr. Bright. That is what is needed.

Ms. <u>Kelly.</u> Will more equitable distribution of equipment and supplies help to address the inequities we are seeing in the impact of COVID-19 on communities of color?

Dr. Bright. Yeah, absolutely.

Ms. <u>Kelly.</u> And do you feel in the last bill that we passed, we made sure that there was passed in the bill better data, as far as race and not just who died, but who was hospitalized and so on and so forth? Because we are hoping that better data will inform policy. How do you feel like that will help?

Dr. Bright. I think that is very important. I think it is a wise move.

Ms. <u>Kelly.</u> Okay. Good. And we are supposed to get a report 21 days from when the President signed the bill, then 30 days, and then 180 days.

Dr. <u>Bright.</u> I am not aware of those guidelines. It comes in a different area, but I think reporting and oversight of that is important.

Ms. <u>Kelly.</u> And then lastly, you have been sitting in that seat for a while, but is there anything that we haven't asked you that you want to say?

Dr. <u>Bright.</u> It is a really important question, and I have thought a lot about that. I want to, I think, highlight the things I talked about in my opening statement is, we need transparency in the science, and America needs to know the truth. This is a devastating pandemic and not just for health, but also society, our economy, our jobs, our livelihood. And if we do not take seriously the call for action to put specific things in place, a coordinated national plan for testing and response, an equitable distribution of these limited supplies, and ramp up and prepare for what will be a very devastating fall if we don't have the right supplies in place and raw materials, then this virus will overcome us

in significant ways still.

So we have limited time. My message is, we have limited time. We have the ability to do it. We have the greatest scientific minds in our country to do it. We need to listen to them, put the plan in place, and everyone get busy stopping this virus.

Ms. <u>Kelly.</u> Right. I know it is very -- I have had three people in my family with it, and I lost my uncle, maybe, like, 10 days ago now from the virus. So it does definitely touch everybody. Thank you, and thank you for your patience.

Dr. Bright. Thank you.

Ms. Eshoo. The gentlewoman yields back. The minority reserve?

All right. Then we will go to the gentlewoman from California, Ms. Barragan, for her 5 minutes of questions.

Ms. <u>Barragan.</u> Thank you, Madam Chairwoman.

Dr. Bright, one striking aspect of your account in your complaint to the Office of Special Counsel is the contrast between the public updates by the President and Secretary Azar on COVID-19 versus the analysis you and other experts were providing behind the scenes. I would like to explore this disconnect, and ultimately that the administration shared information that I believe was misleading. We need to do this to better understand what happened, and how we can ensure that the administration provides the public accurate and constructive information going forward.

Dr. Bright, you had learned of the COVID-19 threat by early January. Is that correct?

Dr. Bright. Yes.

Ms. <u>Barragan.</u> And according to your complaint, it was clear to you, almost immediately, that the, quote, "virus was highly contagious, spreading rapidly, and could

have a high mortality rate," end quote. Is that correct?

Dr. <u>Bright.</u> We were learning that from the outbreak in China at the time, yes. And each day we learned more information, it was actually more concerning.

Ms. <u>Barragan.</u> And the World Health Organization confirmed your view that the virus was a big problem in a January 20 call to agencies, including HHS. Over the course of January, you pressed HHS leadership about the urgent need to devote increased resources to address the outbreak. On January 23rd, you briefed Secretary Azar directly that funding, personnel, and clinical specimens, including viruses, were critically necessary to begin development of life-saving medicines needed in the likely event the virus spread beyond southeast Asia. Yet, on January 24th, in a tweet regarding the virus, the President asserted, quote, "It will all work out well," end quote.

On January 29th, Secretary Azar reportedly told the President that the epidemic was, quote, "under control," and the President echoed that comment publicly the following day. This disconnect between the analysis of public health experts and the public statements by the administration leaders continued through February.

Let me give you some more examples. In early February, you continued to raise the alarm bell within HHS about the imminent mask shortages and the lack of preparations for the wave of infections that you saw coming. Thank you for doing that. Yet, in public remarks on February the 10th, President Trump stated, "It looks like by April, in theory, when it gets a little warmer, it miraculously goes away," end quote. Then he added, "I think it is all going to work out good. We only have 11 cases, and they are all getting better," end quote.

You said that experts knew that the number of N95 respirator masks needed to protect healthcare workers and other Americans in a pandemic was close to 3.5 billion.

Yet, in testimony on February 25th, Secretary Azar said the U.S. would only need 300 million N95 respirators. That is an order of magnitude so much less than what you stated.

Throughout February, you continued your warnings. I would say that your hair was on fire about the dangers millions of Americans faced from this virus. But on February 26, President Trump characterized the number of cases this way. Quote, "When you have 15 people, and the 15 within a couple of days is going to be down to close to zero, that is a pretty good job you have done," end quote. By March 10th, there were over a thousand diagnosed COVID-19 cases in the United States, and over 30 deaths had been attributed to the virus in this country. Yet, the President that day told the country, quote, "It will go away. Just stay calm. It will go away," end quote. He couldn't have been more wrong. Today we have over 1.4 million cases.

Dr. Bright, what impact do you believe that statements by the administration leaders downplaying the COVID-19 crisis throughout February had on the ability of our public health system to mount an effective response to the COVID-19 virus?

Dr. <u>Bright.</u> I believe Americans need to be told the truth. I believe that the best scientific guidance and advice was not being conveyed to the American public during that time. I believe by not telling America the truth, or being fully transparent regardless of where the information was coming from, people were not as prepared as they could have been and should have been. We did not forewarn people. We did not train people. We did not educate them on social distancing and wearing a mask as we should have in January and February. All of those forewarnings and all of those educational opportunities for the American public could have had an impact on further slowing this outbreak and saving more lives.

Ms. <u>Barragan.</u> Well, thank you, Dr. Bright. I want to thank you for sharing your perspective with us today. I hope that over the course, I hope that your courage in coming forward helps our country forge a better path than the disastrous course charted by this administration to date. I yield back.

Ms. <u>Eshoo.</u> The gentlewoman yields back. Minority reserves?

Pleasure to recognize the gentlewoman from Delaware, Ms. Lisa Blunt

Rochester --

Ms. <u>Blunt Rochester.</u> Thank you.

Ms. <u>Eshoo.</u> -- 5 minutes for questions.

Ms. <u>Blunt Rochester.</u> Thank you, Madam Chairwoman, and thank you, Dr. Bright, so much for your testimony, but also for your courage here today. As you can hear from our colleagues, there is not a person in this room or in this country who hasn't been personally touched by COVID-19. And your statement that we need to be told the truth is probably the most important statement we have heard all day, because we know that if we don't face it, we can't fix it. So I want to personally thank you on behalf of all Americans for your courage to testify before us today.

And I want to say that my focus for this hearing is really on three things: Number one, what have we learned? Number two, what do we need to do now? And number three, what can we do to prevent or mitigate the risks of an additional wave of COVID-19?

It is clear since January of this year that there has been a failure on the part of the administration to use the scientific evidence that has been prevented by the Nation's top public health officials to take comprehensive -- and I will use that word again -- comprehensive, appropriate, and urgent action to respond to COVID-19.

One of the most pressing outstanding needs that has yet to be addressed is the

need for a national testing strategy. Dr. Bright, in your testimony, you mentioned the need for such a strategy that ensures tests are, among other things, available to everyone who needs them. I, along with Congressman Collin Peterson and Representative Vela from Texas, wrote a letter to the Democratic and the Republican House leadership in the House and the Senate, and we really impressed upon them the need for outlining the importance of a robust testing plan for testing and tracing. And while current testing capacity is 1.6 million diagnostic tests per week, healthcare experts say that we are woefully short of the estimated 30 million tests per week that we need to get America back to work as safely and confidently as possible, and to avert or mitigate a second wave of COVID-19 which is one of my biggest concerns.

Dr. Bright, what are the immediate steps that HHS needs to be taking to ramp up testing capacity now through the fall, and what targets should they be held accountable for?

Dr. <u>Bright.</u> I think what is really interesting about the testing story that gets lost in the narrative sometimes is the confusion about the different types of tests. There is an antigen test that tells you if you have the virus in you. There is a PCR test that says it is made of fragments of the virus, and there is an antibody test that looks at your antibody titer to try to tell you you have been exposed already and may be immune to that, the virus.

There is a lot of confusion, and I think the first thing HHS needs to do is determine which of those tests is, most important, to achieve which objective. If the antigen test is what is needed because it is faster and lower cost, and more readily available in some cases, what does it tell Americans? What does it tell employers? What does it tell schools about the potential for an individual who has a positive or negative on that test

and their potential to have a different result the next day or later that day?

There is a lot of confusion about these tests. So I think the first thing that HHS should do is determine the type of test, and how that test would be used effectively and then make sure that we have enough of those types of tests, and they are in the right place, and the people using them know what the data tell them and how to do it effectively.

I think there is a lot of confusion there, and they need leadership in HHS to distinguish those challenges and clarify that for the American public. It is not just a test. There are many different tests, and they tell you different things.

Ms. <u>Blunt Rochester.</u> Thank you. Thank you. And why do you think that our Nation has struggled with ramping up the testing capacity, unlike other countries? And were there contingencies in place or a backup in light of this situation we are in now?

Dr. <u>Bright.</u> I think part of the struggle is waiting too late to think about it and to get it started. And when we have had conversations with some manufacturers, they have been very creative in how they can ramp up. Another part of the challenge is we have allowed many of these capabilities to be offshored. And, so, we have much more capability in expanding domestic capacity when it is in our country, and we can ramp up and bring innovation to those companies in the U.S. But if the supply chain is offshore, and there is a global need and competition for that supply chain, that also significantly impairs our ability to ramp up.

Ms. <u>Blunt Rochester.</u> Again, I just want to thank you so much for the time that you have contributed to our country, but also, for your courage to be here right now. Many of us are challenged, as Democrats and Republicans, to make sure that our country is safe and healthy, and it really is -- it really -- I don't think I have ever in my lifetime seen

anything like this, and it does require us to look back, and at the same time look forward, and make sure that we have what we need as a country. So I thank you again, and I yield back the balance of my time.

Ms. <u>Eshoo.</u> The gentlewoman yields back. Does the minority reserve? Voice. We don't have any further questions.

Ms. <u>Eshoo.</u> All right. Then it is a pleasure to recognize the gentleman from Illinois, Mr. Rush, for his 5 minutes of questions.

Mr. Rush. I want to thank you, Madam Chair -- Chairwoman.

Ms. <u>Eshoo.</u> Do you have your microphone on?

Mr. Rush. I have it on now.

Ms. Eshoo. Good. Now I can hear you. Okay.

Mr. Rush. I want to thank you, Madam Chairman.

Dr. Bright, it is so good to see you. I have been watching you this morning, and it just amazes me about your courage and your insight and your commitment, and I am just so delighted to be in the same room with you. Your contributions are impressive, and your reports on how the scientific process was pushed aside for short-term political points are extremely troublesome to me and to the American people, I am sure.

I am absolutely convinced that both you and the Chinese doctor, Dr. Li, the doctor who first raised the alarm over the coronavirus while in China, you two will be remembered as two titans of this pandemic. You took the path that was right rather than the path that was easy, and I commend you for it. And that said, Dr. Bright, it has been widely reported that President Obama's White House National Security Council left the administration a detailed, very thorough document on how to proceed through a pandemic. And did you have any input in that playbook?

Dr. <u>Bright.</u> Yes, sir, I did. A number of our agencies across the government had input in that playbook.

Mr. <u>Rush.</u> And as far as you know, have any of those recommendations been enacted upon in this administration?

Dr. <u>Bright.</u> I believe some of those principles have been reviewed and considered, but I think the playbook has changed in this outbreak. I don't think they followed that playbook.

Mr. Rush. Like you, I think it is critically important that we focus on the path forward. While we must learn from the past and correct as they occur, our response has to be forward-thinking, forward-moving. And I am the sponsor of a bipartisan COVID-19 Trace Act. I have been working on developing a comprehensive, \$100 million strategy for mobile testing and door-to-door tracing. And my legislation -- my bipartisan legislation empower community groups to hire and train and pay workers to engage in testing and contact tracing. It prioritizes hotspots in medically underserved areas, as well as entities who are hiring locally, and as such, I was very interested in your view on the national testing and tracing strategy. In your testimony, you said, the virus is out there. It is everywhere. We need to be able to find it, to isolate it, and to stop it from affecting more people. And with that, I could not agree with you more.

My question might be outside of the scope of the NIH or BARDA, I believe that it should, that it is a question that is relevant to today. And I need to hear more about what you, as an expert on pandemic outbreaks, believes should be our national strategy for testing and tracing.

Dr. <u>Bright.</u> Sir, I think it is important. You are spot on, that we need to have a strategy that everyone follows, the same strategy, to test for where the virus is, who is

infected with this virus. Then we have to appropriately isolate that person and quarantine so they don't infect others. And we rapidly need to trace their contacts, understand who they may have been exposed to, and be able to test those individuals. And if they have been infected as well, we need to be able to isolate those.

Through concerted, coordinated effort across the country, we can be able to identify where that virus is, who has been exposed, give those people proper treatment and isolation, and can slow the spread of this virus significantly. But that has to be in a coordinated way. We have to have the right tests and enough of those tests. It is not something we do once and we are done. It is something we have to continually do in a community. So it is not just that we need one test for every person in America, we need multiple tests, and the right types of tests, and we need the right types of individuals and professionals who know how to use those tests to trace the individual contacts and to isolate that virus and stop it from spreading.

Mr. Rush. Well, I certainly thank you so very much, and thank you for, again, for being here and letting the American people know what really is going on in our Nation with this pandemic. I thank you. And Madam Chair, I yield back the balance of my time.

Dr. Bright. Thank you.

Ms. <u>Eshoo.</u> I thank the gentleman. The gentleman yields back. There is no request from the --

Mr. Walden. We are out of speakers.

Ms. <u>Eshoo.</u> You are out of speakers. Okay.

It is a pleasure to recognize the gentleman from Arizona, Mr. O'Halleran, who is a member of the Energy and Commerce Committee, and according to our rules, we can, as

members of the full committee, we can waive onto a subcommittee. And so we welcome you this afternoon and recognize you for 5 minutes of questions.

Mr. O'Halleran. Thank you, Madam Chair.

Ms. Eshoo. Put your microphone on.

Mr. <u>O'Halleran.</u> Thank you, Madam Chair, and, Dr. Bright, thank you for your remarks today, your insight, your knowledge, and your caring for the American people. You have touched on several concerns I share with my colleagues about how the United States has responded to COVID-19. We must address the health crisis head on if we want to tackle the economic crisis that has overtaken our country.

We are going to need a coordinated, as you mentioned, national testing and contact tracing plan, spearheaded by the Federal Government, to prevent States from competing with one another for resources and planning for hotspot attacks and other issues that will come up. This is the only way that people will feel safe returning to work, eating at restaurants, enjoying Arizona's public lands, and being out in public and close to others. This flexibility piece is critical, and you can't have that unless you have a coordinated process.

In my district, the Navajo Nation has, for months, been going under this process, and it is 170,000 people. The area is the size of West Virginia. So they are not all gathered in a group, though. So this fallacy that only urban areas are impacted is -- and that it can't spread very fast, 16 people died yesterday. And, in fact, on a per capita basis, this currently has more cases than any State in the country, and yet, this hotspot is still not being addressed in the appropriate way. More resources are needed, and they are needed now, and they were needed more than a month ago when we started trying to get this done.

They continue to struggle to see the Federal Government's promised payments in a timely manner. It came through finally, but it has to be timely in order to respond. This will bolster the health system and provide people with water, food, and supplies during this time of great crisis.

Dr. Bright, as an infectious disease expert, what is the one thing that the Federal Government must do to ensure that hotspots, like Navajo Nation, or anywhere else in our country, are successfully mitigated in a timely way so that this virus does not continue to spread throughout communities and to bring back the faith of the citizens of our country, to be able to understand that we will respond quickly with the necessary supplies?

Dr. <u>Bright.</u> Congressman, that is an excellent question. I believe that there is a need to recognize that it is a hotspot, and understand the per capita outbreak of a number of infections in different areas and not treat every area in the United States the same. The rural areas, the less dense areas, are not the same as a dense city, such as New York City. However, you can have just as significant a challenge in a rural area or a less dense area as you described in Arizona.

So I think the first recognition is to get the data across the country into the Federal Government, so they can make the right prioritization decisions and allocation -- equitable allocation of those limited supplies and resources to areas such as yours with a hotspot area. I don't think there is a full recognition yet of how to define necessarily the hotspots in a standardized way across the country. So we need to have the scientists review this challenge and come up with an equitable distribution and recognition of those areas.

Mr. <u>O'Halleran.</u> Thank you, Doctor. I want to point out that this enemy goes much faster than one of our jet planes. Our fighters go fast, but this goes microseconds,

one person to another, and it passes on and on and on. So I appreciate your comment.

But statistics have to be relevant and timely.

Dr. Bright. Yes.

Mr. <u>O'Halleran.</u> In order to be able to do that, it needs a central database.

Dr. Bright, we are currently seeing the number of COVID-19 tests that are being administered increase nationwide. What major hurdles stand in our way from increasing our testing capacity quickly, moving forward, and how can the Federal Government address these now or within a quick period of time? It has taken -- White Mountain Apache are going through a hotspot right now in my district. They cannot get tests, and that is -- they have had 400 cases out of 14,000 people. I mean, this is a critical issue. Please.

Dr. <u>Bright.</u> Sir, I still think we need to recognize the importance of the different types of tests. And when we identify those different types of tests are essential for what we need to do to isolate the virus, or identify people infected with the virus. Then we need to put all efforts into ramping up production of all supplies for those tests.

We found many times that we have ramped up now test production, but we have not thought about the critical reagents that accompany those tests. We haven't thought about the swabs. We are asking equipment -- diagnostic equipment that might normally run 100 tests a day, to run 10,000 tests a day in a 24-hour period. So there hasn't been a real thought-through plan about how to maintain that equipment, and that equipment now is failing in many places.

So as we ramp up capacity to test, and we haven't thought all the way through the raw materials and maintenance of that equipment, those supplies, then we can find ourselves a few days down the road, not having the tests we thought we had, not having

the supply we thought we needed. So again, this is where a coordinated strategy and plan for testing comes into place, not just how to use the tests, but how to make sure we are sustaining that supply, how to make sure that we have thought of every component, if it is a swab, if it is a buffer, if it is a lubricant for the instrument itself, making sure that all of those things are considered and in that national strategy, so we don't ramp up in one area and crash in another. We have to ramp up in all areas at once.

Mr. O'Halleran. Thank you, Doctor, and Madam Chair, I yield.

Ms. Eshoo. The gentleman yields back. Seeing no other Members to speak, I want to close. Dr. Bright, you have been here for just shy of 4 hours of straight testimony, and my observation is the following: I think that you are the finest ambassador in our country for scientists. Your encyclopedic knowledge, the depth and the breadth of it, I think as the American people have listened this morning, that you have given them confidence. You have also issued your warning. And I pray -- and I sincerely mean that word -- I pray that we will work together successfully so that that window that is closing, we will optimize the time that we have while it is still open.

You know, facts are really stubborn things, and sometimes it is uncomfortable to have to deal with the facts that we are facing. But we, the United States, still has more cases, more deaths, by far, than any other nation on earth. And by that definition, we have, in my view, a profound failure. You have given this committee a roadmap today, and we all have been -- witnessed your integrity. So thank you for your service to our country. Thank you for your willingness to testify here today. Thank you for your courage, which has raised your blood pressure with all of what one contends with when you become a high-profile witness. But I think you should rest assured that you have made a difference today. And on behalf of all of my colleagues, I thank you and salute

you and thank you for your family being here as well. Thank you.

Dr. Bright. Thank you.

Ms. Eshoo. I will ask the -- yes?

Mr. Burgess. I was going to ask if I could be recognized for concluding remarks.

Ms. <u>Eshoo.</u> Yeah, I would be glad to. Dr. Burgess, you are recognized.

Mr. <u>Burgess.</u> Thank you. And as I outlined at the beginning of this hearing, there are a number of things that we do need to look into, and I hope that we will. This crisis has been going on for several months. We had an hour tacked onto a budget hearing at the end of February, and then this is the first glancing blow we have had against this crisis. So I welcome the hearing today. I think it is important, I appreciate Dr. Bright being here. I appreciate him bringing his guest.

I do think we need to look into the issue of testing. I simply do not understand how the CDC got so far behind the curve at the beginning, and I would like to know that. But I also feel like there has been -- in previous administration, there was an effort to really regulate what are known as laboratory-developed tests and move those away from clear regulated products to FDA regulated products, and that really did put us behind. The innovators have now stepped up. I am thankful that they have, but we shouldn't have excluded them in the first place. And I think when we look back on this, that is going to be one of the failings at the Federal level. And that is not a recent failing. That goes back to guidances and rules that were issued back in 2012, 2014.

As far as testing is concerned, and the ancillary supplies, there are tests that might just involve taking a salivary sample. That would be great. Spit into a cup, not have to deal with those obnoxious swabs going halfway down your throat. I suspect those are cups are probably in greater supply and more readily available.

And then, Dr. Bright, you will remember I had an interaction with you in March. I have had people pounding on the door with all kinds of ideas. I had people that want to make personal protective equipment. They turned their furniture shop into a PPE manufacturing shop. They had difficulty getting through the bureaucratic cul-de-sacs of the various Federal agencies. I have got a man that has got a breathalyzer test for COVID-19. I don't know whether it works. If it does, it is pretty intriguing. A mobile unit, about the size of a bread box that you can take from place to place. You simply blow into a tube and -- we would have to have more straws. We have outlawed them recently, but that could be dealt with. There are some innovative things out on the horizon.

The vaccine worries me, too, because I recognize there are some illnesses for which we have never found a vaccine -- H1N1. And I realize it is different because that was a flu vaccine, but that did happen in about 8 months if I recall correctly. The outbreak happened at spring break. We didn't know if we were going to be able to open the schools in September, but the vaccine was generally available mid-September to early October, depending on what part of the country you were in.

So that success story gives me some hope that perhaps there is going to be life at the end of this tunnel in the form of a vaccine, but I do welcome that we had the hearing today. I look forward to a number of additional hearings.

The ranking member of the full committee was quite correct to invoke rule 11.

We will keep that as an option going forward. And I thank our witnesses for being here today, and I will yield back.

Ms. <u>Eshoo.</u> The gentleman yields back. Thank you, again, Dr. Bright. And the first panel has completed testimony, and I would just ask the staff to prepare the table for

our next witness, and then we will begin in just a few minutes.

[Recess.]

Ms. <u>Eshoo.</u> Mr. Bowen, you can be seated at the witness table. Good afternoon and welcome to you. I know Members have really missed being together, but we are going to begin our second panel. I want to introduce Mr. Mike Bowen.

Mr. Bowen is the executive vice president of Prestige Ameritech, which is America's largest domestic surgical mask maker.

I want to thank you, Mr. Bowen, for flying from Texas to be with us today. Your story is a very powerful one. And to my colleagues, Mr. Bowen has been, I think, really, he wins an award for tenacity, because over three presidential administrations, he has been banging on the door, warning, asking for, pointing out, that America has a dangerous dependence on foreign countries for products that we need here at home. So this is very important testimony, and we welcome you, we thank you for traveling to be with us today, with all of the extenuating circumstances to travel, and we are very grateful to you. So you are now recognized for your statement, and then we will -- and then you will hear from the Members, and I am sure both your statement will provoke questions and that you will get good ones from both sides of the aisle.

I should add something here, and that is, this issue of our terrible dependence on foreign countries for not only our drugs, our Nation's critical drug supply, but also all of the materials that we have been talking about, is an issue that has been -- is shared, the concern is shared on both sides of the aisle. As I said previously today -- I think it was this morning and not this afternoon -- that we have had bipartisan legislation on it.

But we want to hear from you. We want to hear your story. I think it is a very important one and I know the members will as well. I want to invite at this point the

ranking member to welcome our guest because he is his constituent. So to Dr. Burgess.

Mr. <u>Burgess.</u> Always good to welcome a Texan to our committee. It is always a good day when we have a Texan at the witness stand. We know we are going to hear the truth. I will say, I have been on this committee since 2005. In my second term on the committee, in the year it started, 2007, then-Chairman Dingell had a hearing on the amount of active pharmaceutical ingredients that we imported from other places, in particular, China. Shortly after that, we had a problem with heparin contamination. We have had a number of hearings on this with lead-based toys, melamine in our pet food, and there has been a number of concerns about why we continue to use a supply chain when, from time to time, it is detrimental to us.

So if there is any bright spot in this current crisis that we are in, it may be that finally after 13 or 14 years, we seriously move to make stuff here, be our providers for ourselves, and quite frankly, you know, America first really should mean something. But I welcome you here today, Mr. Bowen. We are anxious to hear what you have to say.

Ms. <u>Eshoo.</u> I think made in America. Anyway, welcome, Mr. Bowen, and it is your -- you have the floor now. You have 5 minutes for your testimony. If you want to place your statement in the record and just speak or read, it is up to you, but welcome and thank you for joining us today.

RPTR DEAN

EDTR HUMKE

[2:02 p.m.]

STATEMENT OF MIKE BOWEN

Mr. Bowen. Good morning.

Ms. Eshoo. It is already afternoon. You need to turn your microphone on.

Mr. <u>Bowen.</u> Good morning, Chairwoman Eshoo, and Ranking Member Burgess.

Thank you for your invitation. It is my pleasure to testify.

My name is Michael Bowen and I am the executive vice president of Prestige

Ameritech of North Richland Hills, Texas. And I have been in the medical industry since

1986 and with Prestige Ameritech since 2006.

Prestige Ameritech was founded by president and CEO, Dan Reese in 2005. I am going to give a brief overview of my interactions with BARDA and its directors, but first I will give you some pertinent mask industry history.

Until 2004, 90 percent of all surgical masks worn, and I am including surgical respirators, were domestically made. That year or around that year, all of the major domestic mask sellers switched from selling domestically made masks to selling imported masks.

Prestige Ameritech was founded in 2005, recognized this as a security issue in 2006. We thought that once America's hospitals learned that their mask supplies were subject to diversion by foreign governments during pandemics they would switch back to U.S. made masks. We were wrong.

In November of 2007 we received a phone call from BARDA, asking for a tour of our mask factory. BARDA was acting on George W. Bush's Presidential Directive 21, the purpose of which was to review America's disaster plans. Brenda Hayden with BARDA gave a presentation which showed that BARDA was concerned about the foreign controlled mask supply. We were thrilled that BARDA had discovered the issue until Brenda said that BARDA was only charged with studying the problem.

We were disappointed but we took consolation in the fact that finally a Federal agency knew that the mask supply was in danger. We were very happy to have an ally. Two years later, I received a call from Brenda Hayden, she started the conversation by saying, we have a situation. Her serious tone caused me to ask her if she was talking about a pandemic. And she said yes. She asked if we could ramp up production and I said, yes. We built more machines, bought an abandoned Kimberly Clark mask factory and tripled our workforce. America's hospitals needed us and we rose to the occasion. We told them about the high cost of ramping up. And they said they would stay with us. Unfortunately, most returned to buying cheaper, foreign made masks when they became available. The company survived by laying off the 150 people who helped save the U.S. mask supply by taking pay cuts and by taking on more investors.

The H1N1 pandemic, this is 2009, 2010 wasn't severe enough to cause the foreign health officials to cut off mask shipments to America so our predictions didn't come true yet. In a weakened state but undaunted Prestige Ameritech continued saying that the U.S. mask supply was headed for failure, we just didn't know when.

In 2004, to give my security story more issue, I formed the Secure Mask Supply
Association. You can find it at securemasksupply.org. Paraphrasing Ben Franklin, I told
three competing domestic mask makers that if we didn't hang together, we would hang

separately, as China was poised to put all of us of business and put the country at even greater risk. Crosstex, Gerson, and Medicom all with domestic mask making factories, agreed and joined the SMSA. Unfortunately, the Secure Mask Supply Associations's warnings were also unheeded.

During my quest to secure the U.S. mask supply I had the privilege of working with three BARDA directors, Dr. Robin Robinson, Dr. Richard Hatchett, and Dr. Rick Bright.

They were helpful and they encouraged me to continue warning people about the mask supplier. I will say a little bit more about that.

After years of doing this, I quit many times and the only reason I kept doing it is because of the directors at BARDA, they would encourage me and ask me not to quit.

They said that they would express their concerns about the mask supply to anyone that I could get to call them, anyone except reporters. They weren't allowed to talk to reporters, which was very frustrating to me.

They also weren't allowed to endorse the Secure Mask Supply Association. Dr. Robinson was going to do so until HHS attorneys told him that it could cost him his job. He called me personally on vacation to tell me that.

I can confirm that the emails in Dr. Bright's complaint are mine. They are merely the latest of 13 years of emails I sent to BARDA in an effort to get HHS to understand that the U.S. mask supply was destined for failure. Robinson, Hatchett, and Bright all wanted to remedy the problem. In my opinion, they didn't have enough authority. Their hearts were in the right places.

America was told after 9/11 that governmental silos had been torn down so that different Federal agencies could work together for national securities. But I didn't see any of that. The DOD, the VA, the CDC, and HHS could have worked together to secure

America's mask supply. I had suggested this to BARDA and to the CDC on several occasions.

I will be happy to answer any questions that you have about Prestige Ameritech, the U.S. mask supply or my interactions with BARDA, the CDC or Rick Bright. And again it is my pleasure to be here. Thank you.

[The prepared statement of Mr. Bowen follows:]

****** COMMITTEE INSERT ******

Ms. <u>Eshoo.</u> Thank you very much Mr. Bowen, again for traveling across the country to be with us and for your testimony. We will now move to Member questions an I will recognize myself for 5 minutes.

You already touched on your acknowledgment of your emails or description about your actions that were in Dr. Bright's complaint so I will move past that. To the best of your knowledge, is the section of Dr. Bright's complaint about the mask supply accurate?

Mr. Bowen. Yes.

Ms. <u>Eshoo.</u> Should HHS and the administration have been able to foresee, in your view, the mask shortages caused by the pandemic?

Mr. Bowen. Yes.

Ms. Eshoo. How many of your mask lines are not activated right now?

Mr. <u>Bowen.</u> Four.

Ms. <u>Eshoo.</u> Four. My goodness. And as we have a run, a run on supplies, you have four lines that could be working and manufacturing high grade masks for those that need them in our country?

Mr. <u>Bowen.</u> Yes. But not like turning on a light switch. It is a very large process.

Ms. Eshoo. And just spend a moment to tell us what it takes to bring those up.

Mr. <u>Bowen.</u> Well the machines were built --

Ms. <u>Eshoo.</u> If you were to receive orders now to activate those lines, explain that to us. And how many more masks could you be manufacturing right now?

Mr. <u>Bowen.</u> We could be making about 7 million N95 respirators a month. However, again --

Ms. <u>Eshoo.</u> Did you say a month?

Mr. Bowen. Yes, a month.

Ms. <u>Eshoo.</u> Say that again the number of masks.

Mr. <u>Bowen.</u> Seven million N95 respirators per month. But again its not like turning on a switch. We didn't build these particular machines, they were from China and we got them in an acquisition several years ago. So my email to Rick Bright, in that email I said, I think we are in trouble. We have these machines, it would be expensive and hard to get them going, but if we are -- if this is going to be bad, that could happen, so that was my offer.

Ms. <u>Eshoo.</u> Very often, especially for lawyers in courtrooms and elsewhere when you are going ask a question, they say you should know the answer. I think I know the answer to this question, but I want to hear your view on it. We have lost -- we have allowed, we have allowed this supply, this very important supply of protective articles to other countries. Do you believe it is because of saving nickels, dimes and guarters?

Mr. <u>Bowen.</u> I call it chasing pennies to China. It is that insistence --

Ms. Eshoo. And look what it has cost us.

Mr. Bowen. It has cost us lives.

Ms. Eshoo. It has cost us lives. It has cost us lives.

If there is someone that would like me to yield the rest of my time, I would be glad to. If not, we can go to the ranking member of the full committee, Mr. Walden.

Thank you, Mr. Bowen.

Mr. Bowen. Thank you.

Mr. <u>Walden.</u> Thank you, Madam Chair. And I will let you reset the clock too so I don't go over my allotted time. There we go.

And Mr. Bowen, thank you. Thank you for being here. And I appreciate your

testimony, which I read last night. Toward the end of the last panel I received a copy of an email that you sent to Dr. Bright on January 31st of this year. This email appears to be the one included in Dr. Bright's complaint. Though it is one of the exhibits that was not publicly posted by the Washington Post, interestingly enough. Here is what the complaint says, 2 days later Mr. Bowen of Prestige Ameritech sent yet another email to Dr. Bright and Dr. Wolf once again issuing a dire warning about the imminent mask shortage. Among other things he advised, and I quote, "This week we sent 1,000 masks to China and Hong Kong. Now I believe your email actually says a million masks to China and Hong Kong. He continued, quote "In all my years of predicting the U.S. mask supply would one day collapse, I never pictured myself selling masks to China. I have it from two reliable sources China ha begun telling Chinese mask makers not to let masks leave China." close quote. He concluded, I think China will cut off masks to the USA. If so U.S. hospitals are going to have a very rough time as up to up to half the supply is made in China, a horrible situation will become unbearable.

Mr. Bowen. That is my email. Yes, sir.

Mr. <u>Walden.</u> That is your email, okay. In the complaint this is cited an email from L. Wolf to R. Bright on January 29, 2020 I think that citation is obviously wrong since even the complaint acknowledges that it is an email from you, Mr. Bowen, to Dr. Bright, right? That is your email.

Mr. <u>Bowen.</u> That was my email. I don't know how it got to him. I mean, I don't know what email chain you are looking at, but yes, sir, that was my email.

Mr. <u>Walden.</u> I was reading from Mr. Bright's complaint and I just received I think what appears to be a copy of this email. But I think it is cited wrong in the complaint.

The email I received is dated January 31, 2020. It includes all the language that I

read to you from the complaint. And this is exactly why the committee -- and I know it needs all the exhibits cited by Dr. Bright, not just the ones selectively obtained by the Washington Post. And needs the full email chains, not the selective excerpts from Dr. Bright.

Because this document also says and I will quote, this is your email to Dr. Bright and to Laura Wolf, it says, and I quote, "My government strategy is to help the U.S. Government if and only if the VA and DOD become my customers after this thing is over."

Mr. Bowen. Yes, sir.

Mr. <u>Walden.</u> So Madam Chair, I would like to submit the email for the record. We will send you an electronic copy as per our agreements here.

Ms. Eshoo. So ordered.

[The information follows:]

****** COMMITTEE INSERT ******

Mr. <u>Walden.</u> Mr. Bowen, you said you want to help U.S. Government, you want to help Americans get the masks.

Mr. Bowen. Yes.

Mr. <u>Walden.</u> Yet it appears that there seems to be a condition here -- I assume that is because in the past you ramped up, things went away, and people bought from other manufacturers. And so here you are saying and I have it here in the email, my strategy is to help my existing customers and only bring on new customers who are willing to sign a long-term contract. My government strategy is to help the U.S. Government, if and only if the VA and DOD become my customers after this thing is over. And here we were in a crisis as masks were going overseas.

Now, the U.S. government is not your only purchaser, right?

Mr. <u>Bowen.</u> The U.S. Government has never bought from me except during a pandemic, sir. And that email, and that statement was basically saying that I don't want the government to only call me in a pandemic.

Mr. Walden. Okay.

Mr. <u>Bowen.</u> Give me business during peace time so that I can survive to help you during a pandemic.

Mr. Walden. Did you ever ask for a sole source contract?

Mr. <u>Bowen.</u> I have bid on the DOD and the VA business and I continually lose to masks that are made in Mexico, because the DOD does not obey the Berry amendment. They buy foreign masks made in Mexico because Mexico is a friend of ours and it is called a TAA-compliant country --

Mr. Walden. Were your masks NIOSH-n95 approved --

Mr. Bowen. -- make the decision based on price, national security --

Mr. Walden. Sir, if I could reclaim my time.

You said you couldn't turn on these lines of manufacturing very quickly. How long, if you got a big order from the government today, would it take you to produce masks?

Mr. <u>Bowen.</u> Three or four months. And the government wants to do that right now. HHS is asking me to do that. I told them --

Mr. Walden. Three or four months?

Mr. <u>Bowen.</u> Yes. I told them it is going to take 3 or 4 months. They only want masks to the end of year. So I would have to hire 100 people, train 100 people and then fire them at the end of the program. I am not going to do that. Again, I don't want the government to only deal with me when --

Mr. <u>Walden.</u> My time has expired, Madam Chair. I yield back.

Ms. <u>Eshoo.</u> The gentleman yields back.

It is a pleasure to recognize the gentleman from New York, Mr. Engel, for his 5 minutes of questions.

Mr. <u>Engel.</u> Well, thank you. Let me get this down. Voila. Thank you, Mr. Bowen. And thank you, Madam Chair, this is an excellent hearing and it is an issue that we need to focus on because it has repercussions that just continue and continue.

Every day I hear from my constituents, including doctors and nurses serving on the frontlines of this pandemic about the dire shortages of personnel protective equipment and therapeutics, PPEs as they call them. Recently, I helped to author the Preventing Drug Shortages Act with several of my colleagues on this subcommittee, provisions which were included in the recently enacted CARES Act. This all ties together. I have used my role as chairman of the Foreign Affairs Committee to cut through red tape and bring

much needed supplies, like 100,000 antibody tests to New York City from China.

All these actions as you point out, Mr. Bowen, are symptoms of a larger problem most U.S. medical products are manufactured abroad. And as this pandemic has highlighted, this leaves the United States vulnerable in public health crises and obviously poses a national security threat the way I look at it.

So Mr. Bowen, as we can tell this afternoon in reading all about you, the things you have said, the things you have written, you have certainly being a leading advocate for this issue, specifically as it pertains to face masks, which have never been more in demand it than now.

In your written testimony, you note that in 2004 major domestic surgical mask sellers switched from making surgical masks domestically to importing them. I know you spoke a little bit about it, but can go into more detail and explain what prompted this change?

Mr. <u>Bowen.</u> Mask companies wanting to make more profit. So they go to countries -- well, it is not just mask companies, it is people who are in the hospital industry, who are competing for contracts for supplies and it is a bid type situation most of the time. And the way you make products cheaply is to make them in China and Mexico and other places.

So that is why the U.S. mask supply left. It wasn't a coordinated effort, it was a bunch of companies coincidentally deciding to save money at the same time and destroying maybe 4,000 jobs in America and putting the U.S. mask supply under foreign control and that has been my message since 2006 actually.

Mr. <u>Engel.</u> Well it is really unbelievable because it isn't just foreign control it is to a very large degree China control. I am chairman the Foreign Affairs Committee, when

we look at the geopolitical parts of the world, China is probably the biggest adversary to the United States. And not only are we leaving it in their hands, we are leaving it in the hands of an adversary. We are sort of beholden to that country. And I cannot think of much that is more dangerous than that. I am sure you agree.

Mr. <u>Bowen.</u> China controls most of the world's mask supply. China can sell a box of max for \$1 a box -- no, let me say thins, China sells a box of masks for \$1. I don't think anybody is making any profit doing that, because I sell them for about \$5. So their prices are so cheap that they have captured most of the world's mask market.

Mr. <u>Engel.</u> Does the government subsidize, the Chinese Government, the Beijing Government?

Mr. <u>Bowen.</u> I don't know that. All I know is their masks cost less than the materials. If I take my labor costs totally out, I am still nowhere near the cost of their products.

Mr. <u>Engel.</u> Do the Chinese masks meet our standards?

Mr. Bowen. Some do, some don't.

Mr. <u>Engel.</u> What steps can the Federal Government take to incentivize more medical manufacturing of critical equipment like surgical face masks in the United States?

Mr. <u>Bowen.</u> Well, as in a letter that I sent to President Obama, I don't think it requires money. I think it requires the government saying it is a national security problem. It requires the CDC telling America's hospitals they are too dependent on foreign made masks and put them in legal liability. They have to protect their patients and staff. If in a public forum like this you say, this is a national security issue, then those hospitals' attorneys are probably going to get on the ball and tell their hospitals to buy American made products. And they don't cost that much.

The whole market is only a couple of hundred million dollars. This is a \$30 million problem folks, just for people trying to save pennies across the whole United States. It is not some multi-billion dollar problem.

Ms. <u>Eshoo.</u> Would you repeat that again? And lean forward into that microphone so that everybody hears it again.

Mr. <u>Bowen.</u> I said this is a \$30 million problem. It is not billions and billions of dollars. I have never asked for money. In a letter to President Obama, and I wrote President Trump as well, but in a letter to President Obama I said, this isn't about money, this is about information. Tell America's hospitals that they are going to be in a position to not be able to protect their staff and their patients. And their attorneys, those hospital attorneys will tell their hospital to buy American made masks. I don't need your money. I don't need subsidies. Just tell people about the problem.

And that was my problem with BARDA. Not my problem, BARDA wanted do it, they weren't allowed it. This issue needed publicity and try to get them to talk to the infection control prevention magazine -- Infection Control Today. Sorry. I wanted them to talk to the New York Times. Every time we had some kind of a flu bump I wanted them to be able to talk and they couldn't do it.

Mr. <u>Engel.</u> Well, thank you very much, your testimony has certainly been very enlightening. I know the chairwoman and I are kind of looking at each other almost in disbelief. I certainly think that this is something that the Congress has to get involved with and the sooner the better.

Thank you very much for your testimony.

Mr. Bowen. Can I point out something?

Mr. Engel. Sure.

Mr. <u>Bowen.</u> I have watched all of this in a room a little while ago. It seemed like everybody who was beating up on Mr. Bright, Dr. Bright was a Republican and everybody who was defending him was a Democrat. I am a Republican, I voted for President Trump. And I admire Dr. Bright. I don't know what he did in all of his other activities, but I think everything I have heard, and every time I have talked to him, and everything he said here made a lot of sense, and I believe him.

Ms. Eshoo. Thank you, Mr. Bowen.

I now have the pleasure of recognizing the gentleman from Kentucky, Mr. Guthrie for his 5 minutes of questions.

Mr. <u>Guthrie.</u> Thank you very much. I appreciate that. I appreciate you coming today. I have a manufacturing background myself. And I know that the President has asked General Motors and Ford to make ventilators and everybody's business is their business. They make decisions based on what is right for their business.

But during a pandemic there is an upload and if every business person says, we are not going to adjust our lines for a pandemic -- and understand Ford and GM have different access to capital than some others. It is just something that everybody needs to be concerned about, because in a pandemic you do have increased orders, but I understand you want some long-term guarantees as well, but there are a lot of people making decisions. There are people now with their businesses shutdown because of what is going on with the pandemic.

I am just trying to understand the mask manufacturer process. And so my questions are what masks, what type of masks do you manufacture? And do they represent the totality of mask variations solved by the Strategic National Stockpile?

And -- if we can get all these questions in -- do you make all masks that are in demand

that other domestic product producers make?

Mr. <u>Bowen.</u> The only masks that I don't make is a cone style mask, the hard cone style. All the masks like you all are wearing, we make all of those, and we make N95 respirators, yes --

Mr. Guthrie. So you make the N95 --

Mr. <u>Bowen.</u> And our factory used to make 87 percent of the U.S. mask supply.

Mr. <u>Guthrie.</u> So as you know, the Strategic National Stockpile procedure procures medical countermeasures and other supplies to be deployed in a public health agency.

Mr. Bowen. Yes, sir.

Mr. <u>Guthrie.</u> I understand you worked with Dr. Bright at BARDA to get Federal funding to produce masks. Did you have any conversations with Steven Adams, the acting director of the Strategic National Stockpile?

Mr. <u>Bowen.</u> Let me go back before that. The Strategic National Stockpile I met with Greg Burel face to face 5 or 6 years ago. And Greg Burel had no problem whatsoever buying Chinese masks. And I had a conversation with him in the hallway after a meeting when I said, don't you find this a problem that America is dependent on Chinese masks? And he said, no, I don't. And I -- as far as Mr. Adams, I believe I may have emailed him. I don't know, sir. The last 100 days, I have talked to so many people. I don't know what day it is most of the time.

Mr. <u>Guthrie.</u> So you thought it was necessary to through Dr. Bright. You couldn't get anybody else to listen to -- Dr. Bright --

Mr. Bowen. No, no, no. You have go it all wrong.

Mr. Guthrie. I am just trying to find the information so yeah.

Mr. <u>Bowen.</u> First of all, I wasn't looking for business. I opened my email, I don't need your business. My phones are ringing off the wall. I thought of BARDA, Dr. Robinson, Dr. Hatchett, and Dr. Bright. I thought of them as brothers at arms. They knew they couldn't buy my products. I knew that. But they were the only people who believed it.

I would like everybody to go to YouTube put in Michael Burgess and Prestige

Ameritech, you will see Mr. Burgess talking at our factory 10 years ago. You see him say that only 10 percent of the mask supply is made in the United States. I talked to Michael Burgess, Ron Wright, Joe Barton, Patrick Leahy. My associate Matt Conlon talked to Chuck Schumer.

I wrote Barack Obama sub 20 letters, wrote President Trump and everybody in his early administration. Defense Secretary Mattis, General Jeffrey Clark, Nicole Lurie, Anita Patel with CDC, National Academies of Sciences, Greg Burel, hundreds of hospitals, hospital purchasing groups, the hospital risk managers association. Hospital risk managers association, told them the mask supply was going collapse, this is a risk. Nobody listened. Association of Operating Room Nurses, the Defense Department, the Veterans Department, Texas governor Rick Perry, State Texas rep Bill Zedler. By the way, Bill Zedler, Bill Zedler got it. Dozens of reporters, I have been on every news show. I have done this for 13 years. Nobody listened.

And my conscience is clean, Mr. Guthrie. I have been working on this damn issue for 13 years, trying to save lives. Nobody listened and now I am not going to take any of this, what you are trying to do.

Mr. <u>Guthrie.</u> I am not sure what I am trying to do. I am just trying to find out about who you talked with before.

Well, the issue is is that we do have to figure out what is strategic and move forward and there is a lot of stuff, not just masks, a lot of stuff come from China. A lot of our pharmaceuticals and so moving forward, and that is something this committee needs to dig in and move forward and figure out what is moving forward. But I am not sure why you are accusing me of trying do, but I will yield back.

I apologize if I offended you. I didn't intend to.

Ms. Eshoo. The gentleman yields back.

I think my colleagues will agree that my description of Mr. Bowen is that he is a force of nature. I mean, he has refused to give up since what year 2006 you began your crusade?

Mr. Bowen. 2006.

Ms. <u>Eshoo.</u> 2006.

It is a pleasure to recognize the gentlewoman from California, Ms. Matsui, for her 5 minutes of questions.

Ms. <u>Matsui.</u> Thank you very much, Madam Chair, for convening this hearing. And, Mr. Bowen, thank you very much for being here today.

Mr. Bowen. My pleasure.

Ms. <u>Matsui.</u> Mr. Bowen, having been in the PPE business for over a decade, I understand you have worked with several administrations and BARDA directors in your efforts to secure the Federal Government's mask supply. Were you utilizing formal channels with BARDA, including Dr. Bright?

Mr. <u>Bowen.</u> I am not sure what your question is.

Ms. <u>Matsui.</u> Well, were you going towards not only Dr. Bright, but other people above him also at the same time?

Mr. Bowen. No. I never spoke with anyone above the director.

Ms. <u>Matsui.</u> Okay.

Mr. <u>Bowen.</u> Well, actually that is not true. I did correspond with Nicole Lurie one time.

Ms. <u>Matsui.</u> Okay. All right. While facts are not completely known, this reporting indicates there might have been favoritism among administration officials regarding companies awarded supply production contracts.

Mr. Bowen, I understand your company was eventually awarded a \$9.5 million FEMA contract for the production of masks on April 7th.

Mr. Bowen. Yes.

Ms. Matsui. Okay. It was reported in the Washington Post that senior U.S. official said that the government did not have the money to take you up on your offer to help procure masks when you initially reached out in January, but the government alternately awarded contracts to inexperienced manufacturers that charged as much as \$5.55 a piece for masks, nearly seven times the 79 cents per masks you offered. Given this, do you think it is fair to say that the government ultimately lost money by not partnering with Prestige to procure masks earlier?

I think it is an easy question.

Mr. <u>Bowen.</u> Well, yeah. My masks would have cost 79 cents, yes.

Ms. <u>Matsui.</u> Right, exactly. I think even more important is is that we would have had more masks earlier.

Mr. <u>Bowen.</u> Yeah, but in their defense again, it wasn't just like turning on a switch. This was a difficult process and I think they had to look at it like, okay, it is going to take these guys 4 months to ramp up. Is it worth it? And it is an evolving situation.

I don't want to hammer on -- you know, when I was talking to Mr. Navarro, he was acting in good faith, I was acting in good faith and I wouldn't beat anybody up about that.

Ms. <u>Matsui.</u> Okay. Well, thank you, Mr. Bowen. I do still have serious concerns with the way this administration has assessed the risk and need for supplies.

And I believe, Madam Chairwoman, that the committee should continue to investigate the administration's emergency purchasing processes so we are procuring medical equipment and protective gear in the most efficient and transparent way possible.

Now, we are preparing for a second wave of COVID-19 outbreaks that could coincide with the fall flu season. Mr. Bowen, from your perspective you have had experience in this, what gaps remain in the mask supply chain? And where should we be focusing our efforts now to ensure we are prepared to protect public health for the remainder of 2020?

Mr. <u>Bowen.</u> Well, this is an unprecedented situation. There is no way anybody could have made enough masks to protect all of American citizens. But we could have done a lot better to -- we could have protected America's healthcare workers and patients. And that is more where my world is. That is the products that we make and that is what we have tried to do.

And in this pandemic, for instance, we were making 75,000 respirators a month.

That is not a lot. And we have been making them 10 years, we just couldn't get business because our products are made in America and they are more expensive.

Now we are making 2 million, from 75,000 to 2 million, we are bringing on another 2 million. And these are machines that we have built. So you know -- I have seen a lot of people kind of like what he was saying, you got four machines, what is up?

Why are you not running those machines? We are not sitting on our hands, folks. We have gone from one shift to three, we have gone from 80 people to 200. We are working our tail off and producing millions and millions of products.

Setting those machines up is going to be difficult, and expensive, and it requires a long-term commitment from a partner, not somebody who can just say, hey, do this.

Because we are a small business. Again, I am not 3M. And if we do this -- my partner and I euphemistically called it a suicide mission. Yeah, okay, let's go. Let's hire 100 people and order truck loads of material and then somebody says the pandemic is over and we are stuck with it again. We don't want to do that.

So we are not mercenary. Like I say, my conscience couldn't be any cleaner. You know, I have been telling this message forever. For somebody to say you could have done better, I am offended by that.

Ms. Matsui. No, I am not saying that at all.

So thank you very much, Mr. Bowen, for coming before us. You have brought a lot of things to our attention that I think are necessary so thank you so much.

Mr. <u>Bowen.</u> It was my pleasure, my pleasure to be here.

Ms. Eshoo. The gentlewoman yields back.

It is my pleasure to recognize the gentleman from Virginia Mr. Griffith, for his 5 minutes of questions.

Mr. Griffith. Thank you very much, Madam Chair.

I represent that line of Virginia down there on the south side right next to North

Carolina and a lot of our folks had experience in the industry, in the textile industry,

before both Mexico and China did the same thing that they have done to you. And they

have ramped up and they are making all kinds of masks and so forth. And their concern

is is if we ramp up, will there be something down the road where buy made in America.

And I agree with you on that. We need to figure out a way to do that, not only on masks and PPE but on drug supply, et cetera. We need to make sure a significant portion of that is made in the United States so we don't find ourselves in this situation again.

That being said, your phone is ringing off the hook. And I think maybe you have already answered this, but if you could just briefly just state why. If your phone is ringing off the hook, why do you need to have a guarantee on the other end, knowing that the policy is going to shift, but we may not be able to give you a contract in advance.

Mr. <u>Bowen.</u> Well, for me to hire the people and build the machines, I can't do that for a temporary need.

Mr. Griffith. So you don't have the machines built right now?

Mr. <u>Bowen.</u> No. I am saying to go more than we have already gone, which we have already built as much as we can risk.

Mr. <u>Griffith.</u> Okay. But you said you had four lines sitting empty so I thought the machines are already there. Is that not accurate?

Mr. <u>Bowen.</u> Yeah, yeah. Please ask your question again, I am confused.

Mr. <u>Griffith.</u> I am trying to figure out understanding that how somehow the policy is going to change. We can't guarantee you a contract, but I think everybody agrees we have go to have more made in America.

Mr. Bowen. Right.

Mr. <u>Griffith.</u> Why not ramp up with the understanding that the policy is likely to change and I think it will change, because I think we don't -- whether it be masks, or other PPE, or drug supply, we are going to have to have a significant portion of these items made in the United States going forward.

Mr. Bowen. Yeah.

Mr. <u>Griffith.</u> Knowing that, and your phone is ringing off the hook, why not ramp up those four lines?

Mr. <u>Bowen.</u> Because one day the pandemic is going to end and the usage will go down to the basement again where it was. There will be 10 times less usage and I will have all these machines, and people, and these materials that and have nothing do with them. And that is what happened to us before. This is a very difficult thing to ramp up.

Let me say this again, let me remind you that we have ramped up. We have gone from making 75,000 respirators a month to about -- in 40 days we will be ramped to making 4 million respirators per month. So don't concentrate on these four Chinese machines that we really don't know much about and would be a total pain of going, on top of I am trying not to kill my business partner who is in charge of getting all this stuff done.

He is working 20 hours a day now with all the projects we have already got, now to dump on this on top for some business that may or may no come, absolutely not.

Mr. <u>Griffith.</u> Well, I would say to you that I believe I think the folks in my district who are doing this, there are four or five companies that have retooled and gone back up, not to your size, but --

Mr. <u>Bowen.</u> They are making things that look like masks. They are not making masks. They are making things that look like masks.

Mr. <u>Griffith.</u> One of these companies used to make masks before they got run out of the industry. With that being said, I believe that Americans are going to be wearing masks a lot more at various places, movie theaters and so forth. I don't think

the number is going back down.

All right. In your testimony you stated that in 2009 you were instructed by then BARDA director Brenda Hayden to ramp up mask production to respond to H1N1 pandemic. Did you have a contract with the Department of HHS to produce masks at that time? And if not, why not?

Mr. Bowen. No, we didn't and --

Mr. <u>Griffith.</u> Okay. The after H1N1, did you continue to produce masks for the purposes of restocking the Strategic National Stockpile?

Mr. <u>Bowen.</u> I can't do that without the Strategic National Stockpile wanting to buy them.

Mr. <u>Griffith.</u> Did you have conversations with BARDA, SNS, and HHS at that time about supplying the masks for the national stockpile?

Mr. <u>Bowen.</u> I have talked to Greg Burel on many occasions, sir. And have I also offered those machines to him. And I have offered those machines to the Department of Defense.

Mr. <u>Griffith.</u> You are just going to give them the machines or you are going to give them production?

Mr. <u>Bowen.</u> No, no. Listen it on this, here is what I wanted to do. I wanted CDC, and VA, and DOD to get together. I had four machines. I had very little money and they could make a whole bunch of masks and for years -- I have 13 years worth of emails, I can document all this stuff -- I said to the CDC, hey, we can fix -- we can make sure that the Department of Defense and the Veterans Administration always has masks. I have got these four machines sitting here doing nothing.

Mr. Griffith. You were willing to give them production but not the machines.

Mr. Bowen. No. Well, let me finish the.

Mr. Griffith. I am just trying to sort it out.

Mr. <u>Bowen.</u> Well, here is what I was going to say. Let's use one machine, it will make your whole annual usage for one machine and we will let three of them sit there in our factory just ready to go. When you need them, we can turn those things on. And I couldn't get anybody interested in them.

Mr. Griffith. Were you going to give them to them or lease them?

Mr. <u>Bowen.</u> It didn't matter. I didn't have any money in them. I said, give me your peace time military hospital business and we will give you these machines, they will just sit there. Now, we would have had to have had some kind of a plan kind of a plan, you know, to get materials and thing like that. But I was basically saying, we have got a warm base operation and it is not going to cost you guys anything. I made that offer to several agencies.

Mr. Griffith. I see my time is up. I yield back, Madam Chair.

Mr. <u>Bowen.</u> And by the way, forgive me for being angry. I am angry because I have done this for so, so long. And I have been ignored for so long and I apologize.

Ms. <u>Eshoo.</u> Well, Mr. Bowen, I don't think you need to apologize, at least that is my view. I think shame on us. I think shame on all of us that we have allowed this to happen. And this is powerful testimony. It underscores what we need to do, the position that we are in, our crippling dependence on foreign countries for what is -- we all realize now with this pandemic what has been laid bare.

Mr. Bowen. I totally agree.

Ms. <u>Eshoo.</u> So your testimony is I think some of the most important testimony that Congress could be hearing.

I now have the pleasure of recognizing the gentlewoman from Florida, Ms. Castor, for her 5 minutes of questions.

Ms. <u>Castor.</u> Yeah. Thank you, Mr. Bowen, I think you heard Dr. Bright as well this morning say the inaction has cost us lives. And I relayed some of the -- what I understand is that you were first contacted by the Department of Homeland Security in January because they wanted masks for airport screeners. Is that correct?

Mr. <u>Bowen.</u> Yes. And let me clarify. That was probably a low level purchasing person looking for products. And a lot was going on. And I am trying to figure out if this is real. And so they were asking for masks. And I said, I can't help you. But I said tell me, just tell me as two Americans over the back fence, are you worried about this? And he said, I am really worried about it.

Ms. <u>Castor</u>. So that flipped a light switch for you in January?

Mr. <u>Bowen.</u> That and a lot of other things. At the end of January my phone started exploding. And it was really weird. It was Chinese Americans calling to buy masks and they were sending them home. So -- by the way, the reports that I was sending masks to China is inaccurate. I was sending masks to Americans who were sending masks to China.

Ms. <u>Castor.</u> And then I understand that you began emailing with Dr. Bright in -- was it January 26 you emailed Dr. Bright and said that here in America our mask supply is in imminent risk.

Mr. <u>Bowen.</u> Yeah. Again, as I said in my opening statement, those emails were just the latest of 13 years of emails to the directors of BARDA. I consider them my only allies. I couldn't get anybody in else in the government to understand the issue, they understood it. So any time something would happen, we get a flu or the MERS comes

out in the Middle East or whatever I would send them an email, hey is this a big one? Should I ramp up?

Ms. <u>Castor.</u> And then Dr. Bright, as he testified, he elevated your concern and sent it to Dr. Robert Kadlec, the HHS assistant secretary for preparedness and emergency response. Did you hear at that point from Dr. Kadlec?

Mr. Bowen. No, I never met him -- or never talked to him before.

Ms. <u>Castor.</u> And do I understand from the accounts you have previously provided, you did not hear back really until a month later when you received a form letter from FDA?

Mr. <u>Bowen.</u> I don't relate those two events. And the timing I would have to go back and look at emails. But the form letter from the FDA, I don't think had anything to do with those other things. I think that was separate.

Ms. <u>Castor.</u> Well, here is the frustration that I have. This continues to be a problem. After you sent that original notice email and Dr. Bright elevated it to our assistant secretary for preparedness and emergency response, at the end of January, it is February, March, April, May. And what I heard from my hospitals just today and yesterday N95s are still very difficult to procure. They are in dire need for N95s. Another, my community health center, we continue to struggle to get N95s and there are so many folks trying to sell knockoffs.

And one of our largest health systems says the supply chain remains inconsistent and irregular. They remained concerned as they head into the fall. They are going to be squeezed because of flu season and the coronavirus. I mean, why haven't we been able to get a handle on -- I know that they have issued contracts. And what do you have to say? There was a contract apparently issued for \$55 million to a company with no

history of procuring medical equipment for a cost of \$5.50 a piece. What do you know about that?

Mr. <u>Bowen.</u> Just what I read in the paper. Nothing more than you do.

Ms. <u>Castor.</u> What do we say to my hospitals, my nurses, my doctors, the EMTs on the frontline right now that it is months later and they are still struggling with the supply chain and they are worried.

And we have nurses dying who could in to save a COVID patient who stopped breathing. In Detroit area they have 700 staff members in one health system and dozens of doctors, what do you --

Mr. <u>Bowen.</u> I say that we as a country and as the people who are supposed to be on top of this stuff messed up. And it is not what happened in January. It is what has happened since 2007, actually since 2004, you know. Presidential Directive 21 by George Bush identified this as a problem in 2007. I have been on CNN, and Lou Dobbs and Neil Cavuto ad infinitum for all this time. And --

Ms. <u>Castor.</u> Is there not something a little more insidious here when you have an administration who downplayed it, and said that it was going to disappear, and didn't follow the scientists, and told Dr. Bright instead of we respect you and hear you, in fact, we are going to can you, and we are going to reassign you, and we are going to bury you, because you are speaking truth to power? Isn't that a little bit different right now?

Mr. <u>Bowen.</u> Now that you ask, again, I am a Republican, I have been a lifelong Republican. And I am embarrassed by how that has been handled. Like Rick Bright said, it is the scientists we need to be listening to and we are not. That has got to change or more lives are going to be lost.

Ms. <u>Castor.</u> Thank you.

Ms. Eshoo. The gentlewoman's time has expired.

It is a pleasure to recognize the gentleman from Florida, Mr. Bilirakis, for your 5 minutes of questions.

Mr. <u>Bilirakis.</u> Thank you. Thank you, Madam Chair, I appreciate it. Thank you, Mr. Bowen for testifying or presenting today.

Considering the made in China 2025 initiative, can you describe how China is working to corner the Personal Protective Equipment, the PPE market? If you can't, I understand, but if you can, it would be very informative.

Mr. <u>Bowen.</u> Well It is -- America has a weakness for low prices. And the -- I think Chinese prices are so low -- you know, a few years ago I decided to go buy 12 things from Lowe's, Lowe's Home Improvement Center. And I decided I was going to pay whatever it took to buy American. I couldn't make that decision. That decision was taken away from. I bought one item, it was a plunger, a toilet plunger was the only thing I could find that was made in America. What it is is it is the people like the Lowe's, and the Home Depot, and the Walmarts, and the medical companies that the way they want to make money is to lower their costs. The way they lower their costs is to go to China. The line is long and wide for people going to China. And that is why we are dependent on them for everything.

I mean, go look in your closet, look at your tools, look at everything, it is all from China. And the stuff that is in from Mexico, let me say this, half of the U.S. mask supply is in Mexico it has got reservations to go to China. Mexico is not cheap enough. And hospitals are cash strapped and they are bidding out things.

If this hadn't have happened, Mexico would have lost the business and in 5 years China would have made all masks and respirators, like they do the gowns.

Mr. Bilirakis. Thank you.

What safeguards does the U.S. have against substandard PPE infiltrating critical industries like the medical industry, which they have? What standards do we have? What safeguards do we have in protecting our constituents?

Mr. <u>Bowen.</u> Well, that is not a question I can answer. That is up to the FDA.

Mr. Bilirakis. Okay.

Mr. Bowen. And NIOSH.

Mr. Bilirakis. I understand.

Okay. In addition to reports of substandard Chines masks infiltrating markets like Canada and the price gouging that is going on, even here in the United States, I have also seen the discontinued masks for sale on ecommerce sites here in the U.S. along with fake websites and email addresses utilizing American brand names.

How is Prestige Ameritech working to crack down on potential counterfeiting and price gouging of its products, of your products in other words? How are you protecting yourself, your business.

Mr. <u>Bowen.</u> We are a small company. We are a family company. We don't have people to do that. But we never had to do that before, nobody cared about our products. My phone never rang. And now I am working with the FBI on a daily basis because I am getting myself and my business partner have been impersonated.

Mr. Bilirakis. That happens frequently obviously, impersonating.

Mr. Bowen. Yes our website has been copied, our images have been copied.

Mr. <u>Bilirakis</u>. Continue to elaborate on that, please.

Mr. <u>Bowen.</u> Well, here is how it goes. I will get an email from someone -- I got an email from the CEO of a company in Dallas last month that said I am about to wire you

\$1.6 million. I just got a feeling I want to make sure you are for real. I said, that is not me. And someone in India copied our entire website. And what they are trying to do is use our good reputation and our worldwide press coverage now and they are saying, hey, we are with Prestige Ameritech, we are offering you hundreds of millions of masks and wire money to this account. They even have Texas phone numbers. So anybody watching this who is being offered a lot of Prestige Ameritech masks, don't -- don't do it.

Mr. <u>Bilirakis</u>. Okay. Give us some advice, how might Congress further support efforts to protect consumers from price gouging and counterfeit goods? What would you recommend? Do you have any advice for us with regard to legislation, ideas, what do you think?

Mr. <u>Bowen.</u> No, actually, that is something I haven't thought about. If you gave me a couple of days I could think about it.

Mr. <u>Bilirakis.</u> Okay. Well, yeah, if you could get that information to us we would appreciate it very much.

Mr. <u>Bowen.</u> I probably won't remember it after this. If someone could send me a letter, that would be great.

Mr. <u>Bilirakis.</u> Well, Madam Chair, maybe we can communicate with him. Thank you very much, sir.

Mr. <u>Bowen.</u> My pleasure, sir.

Ms. <u>Eshoo.</u> The gentleman yields back. Every member will have the opportunity to submit questions to our witnesses. So you will have those questions, Mr. Bowen. And as timely as possible, then you can respond to the gentleman's question and anyone else who submits one to you.

Mr. Bowen. I would be happy to.

Ms. <u>Eshoo.</u> Okay? All right. Now I would like to recognize the gentleman from Maryland, Mr. Sarbanes, for his 5 minutes of questions.

Mr. <u>Sarbanes.</u> Thank you, Madam Chair. Thank you, Mr. Bowen.

You don't know me, but I feel like I know you because when I listen you to you talk, I think about a lot of people in my district, Republicans, Democrats, Independents who scratch their head a lot of the time and wonder why we can't get these things fixed, why we can't do simple stuff. Why we can't get from point A to point B. And I would say to you that I think your composure today has been remarkable, given the fight you have been waging for 15 years.

In ancient mythology there is a character called Cassandra. Cassandra had the ability to see into the future, but was cursed by Apollo that no one would ever believe her prophesy. And sitting here listening to you today, that is immediately what I thought of. And so thank you for maintaining composure at a time when you could literally, without apology, stand on that desk and just scream at the top of your lungs, I told you so over, and over, and over, and over again.

This is a report from 2007, the U.S. Department of Heath and Human Services discussion with respirator protection device manufacturers on preparedness and surge capacity.

The first page is the bottom line. I am just going to read some of these things.

2007, there will be a significant increase in the need for respiratory protection devices,

RPD during an influenza pandemic. There will be significant needs across all sectors,

healthcare, public safety, business, government, public. Industrial surge capacity of RPD

will not be able to meet need and supplies will be short during a pandemic.

There are several RPD options. I am sure you probably described some of them.

They can be employed to meet the projected needs. All sectors must contribute to efforts to prepare in order to meet the needs for RPD or find safe ways to work around limited supplies during a pandemic.

So this is 2007. This is when you were starting on your crusade, well-founded obviously, given what the Department was identifying as needs at that time. And here we are 13 years later, in the midst of a pandemic, that you and others cautioned us about and we are not ready.

And I have to say that I am embarrassed on behalf of the government's failure to respond to these warnings for so many years. I actually was elected in 2006 and came here in 2007. So my time here kind of tracks your journey to try to get us to wake up to this pandemic, to get things to be made again here in America.

And I have been an advocate for those things, but not enough of an advocate I confess given what you are saying. So I apologize on behalf of the U.S. Government that we have not responded better to the warnings that you have given us for so many years.

And now we are paying for it and the cost is lives unfortunately. So shame on us.

And, you know, 10 years from now they will play back a video of this hearing and will we mark that is the beginning of getting with the program finally and actually changing our policy, and beginning to make things here, protecting our national security as you say. And that is absolutely the right frame in this moment and in the midst of this crisis.

Shame on us if we don't learn from this. And I am sure people said it before, policymakers behind microphones and here we are.

So I hope the public measures our commitment to change on this and to stand up what America needs to do to anticipate these things in the future.

RPTR MOLNAR

EDTR CRYSTAL

[3:00 p.m.]

Mr. <u>Sarbanes.</u> I have almost run out of time, but let me ask you a question. Do you think we can do it?

Dr. Bright. I think --

Mr. <u>Sarbanes.</u> Do you think -- do you believe that if we put our minds to it, that if we collaborate, the private sector and government, to create these manufacturing supply chains, to bring this back from offshore, that we can do what we need to do to keep our people safe? Do you believe that?

Mr. Bowen. I can give you a confident yes.

Mr. Sarbanes. Thank you. Thank you.

Mr. <u>Bowen.</u> Because I am being contacted by a lot of the healthcare organizations that didn't listen, and they are coming to me and saying, you were right, let's fix this.

Mr. <u>Sarbanes.</u> Well, let's fix it. Thank you for being here today.

I yield back.

Mr. Bowen. My pleasure.

Ms. <u>Eshoo.</u> The gentleman yields back. I want the gentleman to know that I especially appreciate your Greek oratorical skills.

Mr. <u>Bowen.</u> Oh, by the way, I would like to say that I didn't know about Cassandra until just recently and was told about that myth by Maryn McKenna. She is the author of "SuperBug," and she has been one of my sisters in arms on this, and she told me about Cassandra.

Mr. Sarbanes. Okay.

Ms. <u>Eshoo.</u> All right. It is a pleasure to recognize the gentleman from Missouri, Mr. Long, for his 5 minutes of questions.

Mr. Long. Thank you, Madam Chairwoman.

And thank you, Mr. Bowen, for being here today.

Earlier I was a little confused, so I want to ask you about what type of masks you make. And I thought you said you did not make the hard masks, that you make more of the masks like we are wearing today when we are not on a microphone. Your FEMA contract for nine-point-whatever million dollars, was that not an N95 mask contract?

Mr. <u>Bowen.</u> Yes. That is an N95, but it is a flat mask, not a cone mask.

Mr. Long. Okay.

Mr. <u>Bowen.</u> It is more of a pocket-style mask.

Mr. Long. Okay. Well, that is fine. I just was wanting some clarification there.

How are those packaged, roughly? I mean, how many are in a box or whatever, when you ship them out to FEMA and they ship them to our States?

Mr. <u>Bowen.</u> Ours are packaged 50 per box, and six boxes per case.

Mr. Long. Okay.

Mr. Bowen. Three hundred per case.

Mr. Long. We have been fighting this battle to get more N95 masks for our States and fighting back and forth between States and getting them from FEMA. So if our State received N95s from FEMA within the last 20 days, let's say, would those have been your masks?

Mr. <u>Bowen.</u> Well, I think they have contracts with multiple people, so they could have been my masks, but not necessarily.

Mr. <u>Long.</u> Okay. Have you heard any complaint about the boxes that FEMA is shipping arriving with missing masks? Sometimes over half the box is filled with filler material. Have you been approached about that?

Mr. <u>Bowen.</u> No. In fact, quite the opposite. We are having hospitals -- Baylor, for instance, in Dallas, got some masks from FEMA, of ours, and they liked them so much they want to start buying them. So we are actually hearing the opposite of that. That is probably --

Mr. Long. Oh, no, no, no, I am not accusing you of shipping out half-filled boxes.

Mr. <u>Bowen.</u> Yeah.

Mr. Long. But the State of Missouri, that is what we are receiving from FEMA.

Mr. Bowen. It probably --

Mr. <u>Long.</u> Boxes that have obviously been cracked open somewhere else, masks removed --

Mr. <u>Bowen.</u> Are those Prestige Ameritech masks? Oh, you are asking me, so you don't know, right?

Mr. <u>Long.</u> No. I have texted the governor here a minute ago, but he didn't --Mr. Bowen. Yeah.

Mr. Long. It just came to me when you were talking about what masks you make a while ago, so I am waiting for an answer from the governor's chief of staff. If that is an ongoing problem with other States, or if you have heard anything about it, but we are just trying to get the bottom of these masks, that FEMA ships out boxes and you open them up and there is a bunch of filler material and half the masks or three-fourths are gone.

Mr. <u>Bowen.</u> That doesn't make sense.

Mr. Long. No, it doesn't.

Mr. <u>Bowen.</u> Yeah. We ship full cases to FEMA, and we are not in the habit of putting fillers in our boxes.

Mr. Long. No, no, no, I am sure your company, don't get me wrong.

Mr. <u>Bowen.</u> Oh, no, no, no, no, I understand that, but I am just saying, if that is happening, it is probably from somewhere else.

Mr. Long. Well, that is what we need to find out, where that somewhere else is.

Mr. <u>Bowen.</u> Yeah. Well, and remember I am only selling them a million a month. They are getting lots, lots and lots and lots, millions and millions from other people.

Mr. <u>Long.</u> We are thankful for anything we get in Missouri, trust me, we tried for a long time to get a hold of them.

Mr. <u>Bowen.</u> I have a little bitty contract.

Mr. <u>Long.</u> One of the two largest hospitals in my district ordered masks, and I am not even -- I am sure they were N95s they ordered. They paid eight times what was the going rate pre-corona outbreak. They got their N95 masks in great shape, everything was fine, the boxes were full, and they were counterfeit.

So that is one of reasons for this hearing here today, trying to sort out some of these things and figure out, like you say, if people are stealing your website, it is obvious, I guess, where some of the counterfeit masks at eight times the going rate are coming from.

I got a little off subject here. Let me ask my question here before I get too far out there on a limb. But it is my understanding that you were able to get connected with the White House economic adviser, Peter Navarro, in March.

Mr. Bowen. I am not sure -- yeah, I guess it was March, yeah.

Mr. Long. That is correct, okay.

Mr. <u>Bowen.</u> Yeah.

Mr. <u>Long.</u> NBC News reported that after you connected with Peter Navarro, that Dr. Bright wrote to his deputy asking him to explore whether BARDA could divert money that was expressly reserved for vaccines and other biodefense measures to buy masks.

Mr. Bowen. Okay.

Mr. Long. According to NBC News, this was an example of how Trump and his top aides have played favorites in awarding contracts and allocating scarce resources. Your company, Prestige Ameritech's deal with FEMA is one of only two identified in the history of the Federal contracting database that explicitly says it was directed by the White House.

My question, what is your response to these allegations from NBC? I am only asking since Dr. Bright's whistleblower allegations accuse others at the Department of Health and Human Services of cronyism.

Mr. <u>Bowen.</u> I am really glad you brought that up, because NBC is -- that article was only one article of two that were critical about us, and both of those articles were written by people who didn't talk to me and got the article wrong. If you would like, I can tell you how that all came about.

Mr. <u>Long.</u> Certainly.

Mr. <u>Bowen.</u> Okay. I was on either NPR or BBC, and one of Steve Bannon's producers heard me on the show and asked me to be on their show. And they called me, and I -- one of their producer guys named George called and said, hey, would you be on Steve Bannon's show?

And I don't know a lot about Steve Bannon, but I know he is a lot farther to the

right than I am. And I said, well, in all fairness, I need to tell you, I am not a Trump supporter. And he said, I don't care.

So -- but I just wanted to get that out of the -- I said, I don't want to be on this show if you think I am a Trump supporter. And he said, no, I don't care.

So then the show went real well, and I was invited back. And I enjoyed talking to Steve Bannon. It was fun. And Steve got it, he got the cause, and he said, I am going to tell a friend of mine, Dr. Hatfield and Dr. Navarro about you guys. And I said, who is Dr. Navarro? And he told me, and I said great, okay.

So then Doctor -- somebody from Dr. Navarro's office called me, and I went through the same spiel. I know you think I am a nut, but that is just the way I am, I want to make sure everybody knows everything. And so somebody from Dr. Navarro's office called and asked me about my company and everything. I said, yeah, I make masks. I said, but, again, in all fairness, I need to tell you, I am not a Trump supporter. In fact, I did an article in the Dallas Morning News 2 years ago that was very critical, and that is going to come out. And he said, I don't care.

So -- and then, to make matters -- to beat a dead horse, when Dr. Navarro called me, I did the same thing. I said, hey, just FYI, this -- you give me a contract, this article is going to come out, and this might embarrass you, just to let you know. And he laughed. Dr. Navarro laughed at me. And he said, send me the article, and I did.

So I have told my friends recently, that article should have been titled "Trump administration gives mask contract to Biden supporter." That is the real deal.

Mr. Long. Okay.

Mr. <u>Bowen.</u> So it was not cronyism, sir.

Mr. Long. Do what?

Mr. <u>Bowen.</u> It was not cronyism at all. And let me tell you, too, Peter Navarro was a gentleman, acted in good faith. He was concerned about the mask supply, so was I, and that is what we talked about.

Mr. Long. I think the team --

Mr. <u>Bowen.</u> No cronyism. And by the way, if you want to take that FEMA contract away from me, please do. I can make a lot more money selling those masks somewhere else. I got a pure heart, sir. I really do.

Mr. <u>Long.</u> No, no, yeah. But I think Trump's advisers and close people, you see them at the press conference out there --

Mr. Bowen. Yeah.

Mr. Long. Several of those people are not Trump supporters either.

Mr. Bowen. Yeah.

Mr. <u>Long.</u> But the President has picked them because they are the best in the business, which I think that is good.

I yield back.

Mr. <u>Bowen.</u> Well, that was the farthest -- farthest from crony. I pretty much tried to talk myself out of that. That is probably why Mr. Navarro said I was difficult to work with. I don't know.

Ms. <u>Eshoo.</u> The gentleman's time has expired. A pleasure to recognize the gentleman from New Mexico, Mr. Lujan, for his 5 minutes of questioning.

Mr. Lujan. Thank you, Madam Chair.

Mr. Bowen, thank you so much for being with us today, sir.

As you outlined in your testimony, you have been raising the alarm about the national security risk from the loss of domestic mask production for some time. Does

the United States need to change that and dramatically increase the manufacturing of medical supplies?

Mr. <u>Bowen.</u> Well, there is a short-term issue and a long-term issue. Right now, there is a lot of masks that are needed, and there are a lot of people going into the business. Unfortunately, a lot of them don't know what they are doing and were making masks out of fabric and other things that don't work.

What I call that is making a life jacket out of lead. You know, I can make a life jacket out of lead and I can paint it orange, but don't go in the pool. Some of these masks that are being made are worthless. So -- I am sorry. I got -- I lost the question.

Mr. <u>Lujan</u>. I think you answered the question, that, yes, the United States needs to take this seriously, and to up manufacturing, but we need to do it the right way.

Mr. <u>Bowen.</u> Yeah. I don't think we need to up manufacturing that much. I just think we need to have it be in the United States so it can't get cut off, like a lot of the Chinese supply was cut off.

Mr. Lujan. Appreciate that, sir.

On January 22nd, you e-mailed officials at HHS and offered to reactivate four of your company's unused production lines for N95 respirators, correct?

Mr. Bowen. Yes, sir.

Mr. <u>Lujan.</u> And what was the response to your offer?

Mr. <u>Bowen.</u> Well, Dr. Bright was kind of all over it. I mean, he really thought this was an important thing. So he said, I am going to forward you to Laura Wolf, she is in charge of infrastructure. And my attitude was, it is a little bit too -- this is too little, too late, but we have got these four machines, we could at least protect some people, maybe our infrastructure.

So they asked me to get with her and tell her what we could do. So I did, I sent a big long email that said, here is what we can do. And then there wasn't a lot of response after that.

And again, I wasn't looking for a contract. I am just trying to be helpful at this point. So -- and again, I think that the travesty here isn't what happened in January, in that time. Laura Wolf is no more responsible than all these other thousands of people that I told, hospitals and everybody I told. So to look at her and go -- or to look at them and go, hey, they didn't listen, and you were right, well, I might not have been right. They are all making decisions in a battlefield situation. I am not going to be too hard on those folks.

I think that the real issue is that, I mean, look at the HHS presentation from 13 years ago. They said, here it is, we are going to have a problem.

And that day -- that is why I say when Brenda Hayden came and gave us that presentation, Brenda, you are preaching to the choir, we can't believe this, this is so wonderful. And then Brenda goes, but we are not allowed to fix it. I said, you have got to be kidding.

So that is why I latched onto BARDA, because they were the only people who believed it, and I kept thinking -- and I will tell you how bad it was and how the responsibility of this goes far and wide, is all three of those directors believed it and knew that it was going to happen, and they tried to work with me.

Dr. Robinson got on a plane and went and talked to a hospital group in Houston because I asked him to. And then because of that, MD Anderson Cancer Center today has enough masks, and they are the only hospital system in Texas -- sorry -- in Houston who does because Dr. Robinson got on a plane.

Mr. <u>Lujan.</u> Mr. Bowen, just because my time is going to run out here, sir. In that communication, it is my understanding that you shared how many masks you could make. And what I was led to believe was 1.7 million masks per week or 7 million per month. Is that correct, sir?

Mr. <u>Bowen.</u> That is correct. If we ran 24/7, yes, sir.

Mr. <u>Lujan.</u> And the price you offered was 79 cents, I think I heard you say earlier?

Mr. <u>Bowen.</u> Well, back then, there was no talk of price. I just said these machines are available. And again, I wasn't looking for a contract. I just said, this is here, remember this, this is here, don't forget.

Mr. <u>Lujan.</u> Earlier in the testimony, though, I think you had said the price was 79 cents for some other --

Mr. <u>Bowen.</u> Since then, we have priced them at 79 cents.

Mr. <u>Lujan.</u> I appreciate that, sir. And when the government finally acted on the need for masks and entered into contracts with less experienced manufacturers, they ended up paying as much as \$5.50 per mask. Is that correct?

Mr. Bowen. I just know what I read in the paper.

Mr. Lujan. I read that as well. It sounds like price-gouging to me.

Look, Dr. Bright testified that there is still a shortage of PPE. There should be no question to everyone in this hearing that there is a shortage of PPE, including masks.

Now, instead of the Trump administration accepting responsibility and ensuring critical PPE is manufactured at the level needed and coordinating with States to distribute PPE where it is needed, the administration left States bidding against one another.

Jared Kushner, who was appointed by the President to be in charge of medical

supplies, said at a press conference, quote, "The notion of the Federal stockpile is that it is supposed to be our stockpile. It is not supposed to be States' stockpiles that they then use." A day after Jared Kushner was on that press conference, the website was changed to reflect his remarks.

Madam Chair, I just want to submit into the record an article from U.S. News & World Report, "States Competing in Global Jungle for PPE."

Ms. Eshoo. So ordered.

[The information follows:]

****** COMMITTEE INSERT ******

Mr. <u>Lujan.</u> Thank you, Madam Chair.

Ms. <u>Eshoo.</u> Does the gentleman yield back?

Mr. <u>Lujan.</u> I yield.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentleman from Illinois, Dr. Bucshon, for his 5 minutes of questions.

Mr. Bucshon. Yep. Thank you, Madam Chairwoman.

Thank you for being here.

So it is just you and 3M that makes these types of masks in the U.S. pretty much.

Mr. <u>Bowen.</u> No.

Mr. <u>Bucshon.</u> I mean prior -- predating the pandemic.

Mr. Bowen. Predating the pandemic --

Mr. <u>Bucshon</u>. There is not much U.S. competition?

Mr. Bowen. Well --

Mr. <u>Bucshon.</u> Not much U.S. --

Mr. Bowen. Well, a formal --

Mr. <u>Bucshon.</u> On a large scale. That is what I am saying.

Mr. Bowen. Not on a large scale.

Mr. Bucshon. Yeah, yeah, yeah.

Mr. <u>Bowen.</u> No, we are all small. The members of the Secure Mask Supply

Association that I started in 2014, there is four of us and then a few others that are small,
but we make probably less than 10 percent of the supply.

Mr. <u>Bucshon.</u> Okay. I mean, this has been a longstanding issue. I mean, your testimony has shown us that. Comments from Members have shown us that. And honestly it is an issue that should have been addressed probably in Congress. I mean,

you know, Congress can tell agencies what to do and how to act and, you know, government contracting rules, agency rules and regulations.

I mean, I have been at this, this is my tenth year in Congress, and it has always amazed me about how not very prescriptive we are in Congress. We give -- it is more broad on what we say. I mean, the recent stuff that we have done is an example.

For the most part, it has turned out okay, but we do give -- we do give agencies a lot of leeway to set rules, regulations, and other things. And it is clear you have interacted with these agencies for years. And even though maybe we knew up here and talked about it, that we had to fix this problem, it was really never fixed. Unless Congress tells them to do it, they are probably not going to.

You know, the other thing is the private sector marketplace, I know you talked about that, how hospitals get products from -- you know, buy cheaper products that are not made in the United States. For your products, say for an N95 mask, the FDA has to approve those products to be used in the United States?

Mr. <u>Bowen.</u> Yes, sir. Well, I think just now, I think that has changed. I believe it is just NIOSH for N95s.

Mr. <u>Bucshon.</u> Okay. But there is a Federal agency that has to certify this is something we --

Mr. <u>Bowen.</u> Yes, sir.

Mr. <u>Bucshon.</u> Right. So, you know, we -- so, I mean, we do have some control over what in certain respects about the quality of the masks that we import into the United States. Clearly there has been, you know, some counterfeits, but probably also some products brought from China and other places that maybe don't go through. Do they go through the same certification process that you do?

Mr. <u>Bowen.</u> Well, they are supposed to, but I know, for instance, every once in a while a Chinese respirator -- well, let me say what NIOSH will do. They will take masks out of the market.

Mr. Bucshon. Yeah.

Mr. <u>Bowen.</u> They will go buy masks and test them.

Mr. Bucshon. Yeah.

Mr. <u>Bowen.</u> And if they fail, you can lose your registration.

Mr. <u>Bucshon.</u> Yeah, okay. And they do that for the Chinese-made masks too, right?

Mr. <u>Bowen.</u> So the Chinese masks, a lot of those have gotten -- lost their registration.

Mr. <u>Bucshon.</u> Okay. And for the Federal -- for the national stockpile, I mean, it seems to me that we are going to have to really consider changing how we deal with that. I mean, you know, you have a stockpile of something, you buy all of this stuff, and then it outdates, right? And then you buy it all again.

Mr. Bowen. Right.

Mr. <u>Bucshon.</u> So what is the outdate on a -- say just an N95 mask. How long are those certified to be used? It is sitting on a shelf, you pull it off there.

Mr. <u>Bowen.</u> They are all different.

Mr. Bucshon. For how long?

Mr. Bowen. They are all different. Five, 10, 15 years. They are all --

Mr. <u>Bucshon</u>. They are all different.

Mr. <u>Bowen.</u> They are all different. But I have never thought that stockpiling was the way to go.

Mr. <u>Bucshon.</u> Right. So this mask here may be -- might be -- you know, if it sat on a shelf in a closed box, it might say on there 10 years.

Mr. <u>Bowen.</u> It might be fine.

Mr. <u>Bucshon</u>. Or it might be fine, Okay.

Mr. Bowen. Yeah, yeah. Or the elastic could rot and --

Mr. <u>Bucshon.</u> Which has happened by the way. I have had people at hospitals tell me they have pulled masks off the shelf and the elastic has popped when they tried to put it on.

Mr. Bowen. Yeah. I don't think stockpiling is the --

Mr. Bucshon. So what do you think we should do? I mean, should we --

Mr. Bowen. Well --

Mr. <u>Bucshon.</u> For example, in the stockpile, if they were outdated, start to outdate, should we be able to sell that stuff before it outdates? I mean, what would be the length of time before an outdate that you would feel comfortable selling a product?

Mr. <u>Bowen.</u> I don't believe in stockpiling, sir, because of all the problems that we have already identified.

Mr. Bucshon. Okay.

Mr. <u>Bowen.</u> I think what we should do is come up with a new kind of mask that can be made extremely fast. Talking about hundreds of millions a week.

Mr. Bucshon. So some innovative stuff?

Mr. Bowen. Absolutely.

Mr. Bucshon. Yeah, okay.

Mr. <u>Bowen.</u> And then ramp up. I presented a program or an idea called Hypersurge to CDC several years ago, and that is what I said. And they said it was the

best presentation of the meeting. Now, we never did it because I couldn't figure out a way to make it profitable, to go and build a machine that is not going to be used.

Mr. <u>Bucshon.</u> Right, right, right.

Mr. <u>Bowen.</u> I am not in that business.

Mr. <u>Bucshon.</u> Yeah. So I get that because, like, I was a heart surgeon before, and so we would have -- we used to when I first started 25 years ago, we would have a stockpile of heart valves, of all sizes.

Mr. Bowen. Right.

Mr. <u>Bucshon.</u> The hospital bought them. They sat there. They had outdates on them. And over the years, ultimately we got a point where they don't stockpile those anymore at the hospital because things would outdate and they would have to get rid of them. So now basically things rotate -- you know, when you are going to do a heart surgery case you can get -- the products will come through, and you will be -- it is consignment, basically, right? You don't buy them anymore.

That kind of what you are saying as a stockpile. You don't stockpile this stuff, but you have a way of quickly getting things --

Mr. <u>Bowen.</u> Well, and a stockpile will work in some situations. For instance, the government does buy masks. The VA and the DOD buy millions of masks.

Mr. <u>Bucshon</u>. Right.

Mr. <u>Bowen.</u> So that can rotate through. So they need a coherent plan, and that is what I tried to present. I said, we have got these four machines. Let's use one machine for your peacetime use. We will rotate that stock for you.

Yeah, that was the plan.

Mr. <u>Bucshon.</u> I am just saying, the U.S. Government could help create a

consistent marketplace for U.S.-made masks.

Mr. Bowen. Yes. Okay.

Mr. <u>Bucshon.</u> We could be part of the solution.

Mr. <u>Bowen.</u> It can be done for healthcare workers. To do it for the whole United States for something that happens every hundred years to protect all of Americans is probably not practical.

Mr. Bucshon. Understood.

Mr. <u>Bowen.</u> But protecting America's healthcare workers is absolutely possible.

Mr. <u>Bucshon.</u> Fair enough.

All right. I yield back. Thank you.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentleman from Oregon, Mr. Schrader, for his 5 minutes of questions.

Mr. <u>Schrader.</u> Hi, Mr. Bowen, welcome. We are doing a lot of things these days that aren't real practical, but we are being forced into them.

Mr. <u>Bowen.</u> It is surreal.

Mr. Schrader. Yeah.

To some of the communications with Dr. Bright, one of the references he made was to a Department of Homeland Security request or communication with you back in mid-January to procure some masks. Could you talk about that just a little bit, what was the nature of that?

Mr. <u>Bowen.</u> Yeah. What I would classify as some sort of a purchasing agent kind of a person, not a high ranking official, called, and said they were looking for masks, I believe for their screeners. And I said, I don't have any, we are sold out.

And then I just asked him, what do you think, is this real? I said, give me your

honest opinion. And he said, I think it is going to be bad. And I said, yeah, I do too.

So to pick up the phone and call Rick Bright --again, these folks to me were brothers in arms. I called him for 15 years -- 13 years. And every time something like this would happen, I would pick up the phone and go, hey, is this it, is this the big one, you know, can I help you? Yeah.

Mr. <u>Schrader.</u> Well, it is interesting that while HHS was not receiving this information in a productive manner, DHS -- at least some folks in DHS were very aware, kind of a situation.

Mr. <u>Bowen.</u> I don't know, but we never -- we were never able to sell the government masks. The government was never a customer of ours until the H1N1 pandemic, and they bought masks from us in emergency, and then never bought again. And tragically --

Mr. <u>Schrader.</u> Well, I would like, just, if I may, I would like to get at that.

Mr. Bowen. All right, go ahead.

Mr. <u>Schrader.</u> But before we do, on February 3rd, there was communication with you and Dr. Wolf --

Mr. Bowen. Laura Wolf?

Mr. <u>Schrader.</u> Yeah. And a comment was made I think -- and Dr. Bright referred to this -- that if we weren't responding now, that our masks would forever be under foreign control. Do you remember that comment?

Mr. Bowen. I don't know.

Mr. <u>Schrader.</u> Okay.

Mr. Bowen. But I --

Mr. Schrader. I was curious what you meant by --

Mr. Bowen. I said that?

Mr. <u>Schrader.</u> Yeah.

Mr. <u>Bowen.</u> Oh, yeah, yeah. What I meant was, if we -- I am glad you asked that question. What I meant was, if we don't fix the U.S. mask supply now, while everybody is thinking about it, while people are dying, we are going to do exactly what we did after H1N1.

During H1N1, I am on the news just like now. And we thought, it is over, we have finally been vindicated. We couldn't believe it when everything went right back. And it is worse. Things are worse now than they were before H1N1.

Mr. <u>Schrader.</u> So getting back to your earlier comments and a bit of what Dr. Bucshon was talking about, you know, pretty clear we need to make some of this stuff in America.

The question is -- you know, I have a little tiny veterinary practice -- or had a very small veterinary practice, and we use masks. The question -- but I was always worried about the dollar, and my job here is also to protect the taxpayer dollar. And, you know, \$5 a box, \$1 a box, you got to think about it at least a little bit.

So what is the right mix there? How do we protect the taxpayer dollar and make sure we protect made in America so that we can react to these --

Mr. <u>Bowen.</u> What I am going to say is going to make no accounting sense.

What I am going to say is that dollar is not real. It should be ignored. They are not making a profit. Just because some country can sell a mask and lose money on it, to us, does that mean we ought to buy that and think that is viable? It is not. It is not. We ought to buy everything that has to do with a critical product, like a mask, in the United States.

Masks costs less now. My masks cost less now than masks cost 30 years ago. You can buy two Class 2 medical devices, which are called surgical masks, for less than a gumball. Okay, the fact that China can make them for 2 cents, or sell them for 2 cents, let's ignore that. It is not real. And it is a threat to national security.

Mr. <u>Schrader.</u> So last question, if I may, and you have alluded to this again, you know, it would be nice to have a stockpile, but a stockpile is not the total answer for what you and Larry were just talking about.

What role does the Federal Government have in setting up maybe a platform that businesses could use when times are tough? In other words, it is not worth your while to set up this platform, produce it for a couple of months, and then try and shut this down, unemploy a ton of people.

Mr. <u>Bowen.</u> Absolutely.

Mr. <u>Schrader.</u> What role could the Federal Government have? We face this with drugs. The chairwoman has been very adamant and concerned about all our active ingredients are made in China or India. That is not a healthy situation either, especially right now.

Mr. Bowen. No.

Mr. <u>Schrader.</u> So what is the role, what is the right public-private partnership with you guys to stand up a platform that could being activated and we bear some of the costs and you guys can tool right up?

Mr. <u>Bowen.</u> Start by tearing down the silos between the CDC and VA and DOD and BARDA and HHS. Get all of those people in a room. Because the VA and the DOD use millions and millions of masks. So that can rotate a stockpile. That can justify having machines sitting here ready to be used.

It needs to be -- there needs to be a coordinated plan between all of these organizations. And then there needs to be -- again, the government needs -- and the government can't tell hospitals to buy American-made masks, but they can sure put them on notice that if you don't, you are probably going to get sued at some point.

You know, I have to laugh. I told my wife the other day, I said I am probably going to spend the last 10 years of my career being a paid witness. Because I think these -- I think all these people who can't protect their employees are going to say, hey, why did you do this to us? You know?

And let me say one more thing too. I have dealt with this thing for so long, and it has been so illogical, and I have tried to figure it out, and who is at fault, who is at fault, and some people ask me that, who is to blame. And I got to the point where it is human nature. It is all of us.

I couldn't convince doctors. I couldn't -- listen to this. I had three directors of BARDA said that, Mike, if you get somebody to call me, I will verify that what you are saying is true. I will tell them it was true.

Mr. Schrader, I couldn't get them to call. I couldn't get hospitals to make that call. I don't think they wanted to hear it. They are programmed to save money.

They are not programmed to say, I want to make sure my masks are going to be here. It didn't compute. I was speaking Greek to everyone.

So to look at this story and look back and blame everybody, I am not even going to do that. I am looking at this pandemic. There is a silver lining. This silver lining is, it has told everybody there is a big problem. And we can fix this problem and never go through this again.

Mr. Schrader. Thank you so much.

Mr. Bowen. Thank you.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentlewoman from Indiana, Mrs. Brooks.

Mrs. Brooks. Thank you, Madam Chairwoman.

And thank you, Mr. Bowen, for being here. It is so interesting to hear. And I want to thank you actually for not blaming and trying to educate all of us as to what you have been telling America and government officials for a very, very long time.

In fact, the chairwoman and I have been a part of -- and I entered into the record many -- a few hearings ago, a group called CSIS, strengthening America's public health security. And the title of this big report that a bunch of professionals came together, a bunch of medical professionals came together, the title of the report is "Ending the Cycle of Crisis and Complacency in U.S. Global Health Security." It was led by Julie Gerberding, who had been a health official. It was led by Senator Kelly Ayotte, who had been in the U.S. Senate. It was all focused on -- and it came out in November of 2019. It came out in November of 2019. And it had a lot of great recommendations that I hope, once again, because I talked about it before, in early 2020, we always go into the cycle of dealing with something, then we become complacent, and we lose focus once again.

And we have done it, you have said, since 9/11. President George W. Bush had a focus on it, tried to bring attention to the mask problem, and others. And then we lost it during the Obama administration. And you wrote lots of letters. And we didn't ramp up.

But I have to tell you that during all of that time participating in that commission, I don't -- we talked about therapeutics, we talked about vaccines, we talked about diagnostic testing. I don't recall anyone ever talking about masks. Okay? They didn't

talk about PPE. And these were all professionals who have been at this, sitting around the table.

And I am glad that Chairwoman Eshoo is agreeing with me. We didn't have that discussion. And now we are all suffering. Our medical professionals, really, and our law enforcement and fire, who are truly on the front lines, are the ones now suffering the consequences, and now we have this huge issue.

I want to talk briefly about the stockpile since you don't believe the stockpile is the way to go. Most of America didn't even know there was a stockpile until this all happened. Most of America didn't know anything about all of these types of things until this pandemic hit.

So we have to have some supply. I come from Indiana, a manufacturing State. We have to have a supply chain. We have to be able to ramp up production. BARDA is all about partnering with the private sector. Many BARDA directors didn't get the job done, based on what you said, not just Dr. Bright, but Dr. Hatchett and Dr. Robinson, they couldn't get the job done.

So what do you -- and we are going to welcome your comments later on, as a manufacturer, and I represent a lot of manufacturers. If we don't have a stockpile and if we don't have dramatic need for PPE, and let's, God forbid, hope we don't, a year from now or 2 years from now, but we might going forward for a while, what is the magic formula about ramping up production when we need it versus when we don't need it?

Mr. <u>Bowen.</u> This is just my opinion. My opinion is to have a small stockpile that can be rotated through America's hospital system.

But as far as the general -- the bulk of the masks, I think we could come up with a different kind of mask that could be made so fast that you wouldn't need to stockpile.

Because the problem isn't -- the problem is, how do you get masks to the right -- how do you get masks to people, how do you get millions of masks to people?

Well, you can do it two ways. You can either have them in a stockpile where they could rot, or you learn how to make them faster. And with a concerted effort, with a group like I was talking about, where you get some people and some smart people in the room, and, hey, make it lucrative, tell the American mask industry, here is what we want to do, I want to -- figure out how to make a million masks a day on one machine.

Mrs. <u>Brooks.</u> But would that be a government contract, or would that be turning on the spigot so that the private sector can call those mask makers, the hospitals can call those mask makers? Because that is what is happening right now.

Mr. <u>Bowen.</u> I think it could be both. I think the government should use the VA and DOD's business as a carrot. DOD and VA are buying millions and millions of dollars' worth of masks. I would love to have that business.

So what I am saying is, me or another American mask maker or combination, gets that business and builds the machine or whatever. You know, I can't think through the whole thing, but there are ways to do that.

Mrs. <u>Brooks.</u> We could use your counsel. And while I have just a few colleagues here, the chairwoman and I have a bill, H.R. 6517, which is all about modernization of the stockpile inventory, and it is about making sure that we can move out expiring products, like expiring masks, before they expire, so that they don't get shipped to States, which I do think is happening, that some expired products are going to States.

But I would encourage everyone, we are trying to modernize the stockpile, improve the stockpile, and we welcome your ideas and thoughts. And certainly wish

that America had listened more to you starting in 2007 when you said the whole HHS information came to light. So thank you.

Mr. <u>Bowen.</u> My pleasure.

Ms. <u>Eshoo.</u> The gentlewoman yields back. The chair now recognizes the gentleman from California, Mr. Cardenas, for his 5 minutes of questions of Mr. Bowen.

Mr. <u>Cardenas.</u> Thank you very much, Mr. Bowen. Appreciate your persistence.

I am going to label you as someone who cares. It sounds like you care about employees.

Mr. Bowen. I care about a lot of things. I love my country.

Mr. <u>Cardenas.</u> Yeah, I was going to get to that.

Mr. Bowen. Yeah.

Mr. <u>Cardenas.</u> I was going to crescendo into how much you love our country. And I think that you love people beyond our country, because we are such an amazing example to the world when we do things to the level of our capability. Do you agree with that?

Mr. <u>Bowen.</u> I totally agree.

Mr. <u>Cardenas.</u> And on this issue, I think you know as well as anybody, we are not doing our part the way we can show the world how to do things right, how to do things for the right reasons.

It sounds to me that you have 13 years of trying to get many people, including the Federal Government, to understand that something is wrong, but it is not going to take genius, nor is it going to take more money than we could put together to do it. It just means that people need to listen, pay attention, and then implement. Is that a --

Mr. Bowen. Yes. I always said it didn't take a lot of money. It just takes some

change. We have got to do things differently.

Mr. <u>Cardenas.</u> I have never been accused of being a genius. Are you a genius, sir?

Mr. Bowen. I am not a genius, and I am not stable, sometimes.

Mr. <u>Cardenas.</u> You are normal?

Mr. Bowen. I am normal.

Mr. Cardenas. Yes, thank you. I figured that.

Mr. <u>Bowen.</u> I describe myself as a goober with a conscience. I am just a normal guy.

Mr. Cardenas. There you go.

When you hear the term "national security," the issue we are talking about today, just specifically masks, does it have something to do with national security? Eighty thousand people have died, and not that every single one of them could have been saved, but 80,000 people have died during this pandemic in America.

I personally believe that number didn't have to be that high had we done more things better, including getting PPEs, or personal protective equipment, specifically masks. The right kind, by the way.

Mr. Bowen. I agree with you.

Mr. <u>Cardenas.</u> So you said something earlier. I have been listening and I really do appreciate you very much and your willingness to come and speak to the American people. Because you know you are speaking to Congress, but you are really speaking to the American people. This is live. Thank God some people are watching.

You said something about stockpiling and you mentioned a couple times, like the VA, et cetera.

I used to own a little business. I wasn't a manufacturer specifically, but I used to own a little business. I know what it is like to care about your employees, to know that if you had to shutter your doors, or shut down a part of your factory, you know families are going to suffer, people you are close to, people that you depended on. So I understand, I am getting that from you, that you do care about a lot of things, including the people that if you are going to put them to work, you don't want to lay them off later for no good reason.

Mr. <u>Bowen.</u> Correct.

Mr. <u>Cardenas.</u> So the issue of stockpile, old-fashioned stockpile, where we allow these kinds of things, for the rubber bands to break or what have you, which that happens, what I envisioned is -- you may have alluded to and I may be wrong -- a rotation of some sort, a cooperation of some sorts, between a big entity like the VA, to actually get a synergy of orders, and then also rotate that stuff -- legally and appropriately and safely and properly -- to other users before those items expire so that we maximize not only production, but we minimize waste, and we actually get those products where they need to be when they need to be there.

Mr. <u>Bowen.</u> If you got everyone involved, all of the big three hospital distributors, like Medline and Owens & Minor and Cardinal involved, and the government really would only have to -- I am thinking through this -- but it wouldn't cost as much as a government stockpile. If these people and us, all the people in the mask industry, if we all carried more inventory and the government subsidized just that part of it, they wouldn't have to buy -- I don't know. I am not an economist. But if we all work together, we could do that.

Mr. Cardenas. And the thing that conservative taxpayers and conservative

elected officials don't like is when you talk about subsidizing. But in reality, the example you just gave, the brief example you just gave, in the long run the taxpayers would end up spending less, the government would end up spending less, everybody would end up spending less, if we just try to figure out how to fill that gap properly.

Mr. <u>Bowen.</u> Right.

Mr. Cardenas. That is what you are talking about, right?

Mr. <u>Bowen.</u> Right.

Mr. <u>Cardenas.</u> So what I would like to invite you to do, and you may have done it already, is I would like to invite you to call my office, Congressman Tony Cardenas, and I will work with any of my colleagues so that we can introduce a bill to actually enlist and require that activity from the Federal Government of the United States, enlisting voluntarily, and required by the government side, to the government to require itself, to damn well do that once and for all.

And I believe that this would be an example about masks, but we are going to be able to cross-pollinate that amazing, cost-saving, life-saving example in other areas of responsibility.

Mr. <u>Bowen.</u> The one thing that would be mandatory for that to happen is for America's hospitals to be willing to pay a little more for a mask, because nobody can match the prices, yeah.

Mr. <u>Cardenas.</u> I know some of my colleagues don't like the word "mandate," but we could mandate that in a way where they welcome it.

Mr. Bowen. Yeah.

Mr. <u>Cardenas.</u> And not with a stick but truly a carrot. But like you said, they just have to understand how it would work in their benefit.

Mr. <u>Bowen.</u> Yeah, I don't know what the solution is, but I think it is probably some sort of a government and private industry partnership.

Mr. Cardenas. Yeah. It is called a PPP.

Mr. <u>Bowen.</u> The medical industry is full of people who care. You guys are people who care.

Ms. Eshoo. Right. The gentleman yields back.

Mr. <u>Cardenas</u>. I yield.

Ms. Eshoo. It is a very interesting line of questions.

I would just place something on the table here, the empty table, and that is that it is one thing for a foreign country, China, you know, to make sneakers and, you know, T-shirts and whatever. But we are talking about commodities that truly are part of our national security. And if anything has laid that bare, it is this pandemic. So this is another category, and we have to treat it as such.

The chair is very pleased to recognize the gentleman from Georgia, Mr. Carter, for his 5 minutes.

Mr. Carter. Thank you, Madam Chair.

Mr. Bowen, very quickly, I have been in and out, so I am still a little confused.

Just help me clear up, because I owe my friend, the chairlady, 2 minutes, so I am going to give those back to her.

But I am still confused about your current capabilities.

Mr. Bowen. Okay.

Mr. <u>Carter.</u> You said you have four lines that are just sitting dormant, sitting empty right now. Is that correct?

Mr. Bowen. We have four idle respirator manufacturing lines, yes, sir.

Mr. <u>Carter.</u> And they are just -- I mean, they are not being used right now?

Mr. <u>Bowen.</u> Yes, but -- go ahead, finish your question.

Mr. <u>Carter.</u> Yes, they are not being used?

Mr. Bowen. Correct.

Mr. <u>Carter.</u> Correct?

So you have said you have already gotten machines for those lines. You don't have to procure them. The only thing you are going to have to do is to get staff in order to use those lines.

Mr. <u>Bowen.</u> No. There is three things. We need to hire a hundred people, we need to train a hundred people, we need to get all the materials for that, and we need to get NIOSH approval. We bought those systems from a defunct Vermont mask company 7 years ago.

Mr. Carter. Okay.

Mr. <u>Bowen.</u> We really don't even know how to use those machines. They are kind of a last resort. And if you will go back and look at my email to Dr. Bright, I said, this would be basically a pain to do, but they are here, and if we need this for infrastructure, let's talk about it.

But what we have done in the meantime is we have gone from making 75,000 respirators a month -- think of that number, 75,000 -- to 2 million. And then in another 40 days, we will be at 4 million, from 75,000. So that is thousands and thousands of percent increase.

Mr. <u>Carter.</u> But you said you bought those. You bought them for a purpose. You bought them to use them, right?

Mr. Bowen. No. Thank you for asking that question. No, they came as part of

an acquisition. We bought a defunct medical company. Those machines came as part of the acquisition.

Mr. <u>Carter.</u> Okay.

Mr. <u>Bowen.</u> And they are made in China. Again -- go ahead.

Mr. <u>Carter.</u> But did you say earlier that your phone was ringing off the hook, you got orders coming out of the yazoo and --

Mr. <u>Bowen.</u> Yeah, yeah, yeah, okay, but I can't go on a suicide mission. I can't ramp up, hire all these people for something that I don't know how it is going to end, or how long it is going to last. And we did this.

You have got to remember, we almost went out of business doing this before. We ramped up and we spent money and built a bigger factory, hired 150 people, built more machines, and then one day the business not only went away, it went smaller than it was. And we had to raise a million dollars, we had to take pay cuts, and we had to fire 150 people.

Mr. <u>Carter.</u> So what you are saying, and I am not trying to put words in your mouth.

Mr. Bowen. I am saying I need a long-term contract.

Mr. <u>Carter.</u> You are saying you are not going to use them, you are not going to fire them up unless you get a long-term contract from the government?

Mr. Bowen. I am not going on a suicide mission. Absolutely.

Mr. <u>Carter.</u> So, that is yes, you are not going to use them unless you get a long-term contract?

Mr. <u>Bowen.</u> Unless I get a customer who is going to use -- commit to use those machines so I don't have to fire a hundred people.

Mr. <u>Carter.</u> So that means that you would have to have a long-term contract from the government in order to do it?

Mr. Bowen. Yeah.

Listen, we have gone from one shift to three, 80 people to 200. We are making four times the products we made. We are making over a million masks a day. Don't you look at me and act like I am sitting on my ass and not firing up four machines. It is not like just turning on a switch. It is putting people's lives that is going to -- I am not going to -- listen --

Mr. <u>Carter.</u> Sir, I understand. I am a businessman, too, and I understand what it takes.

Mr. <u>Bowen.</u> Listen. Let me tell you this. I sat and watched my business partner cry when he had to lay those people off. We are not doing that again.

Mr. <u>Carter.</u> So in order -- so it is going to have to be a long-term contract from the government, though. That is my point.

Mr. <u>Bowen.</u> From somebody.

Mr. Carter. And I get it, from somebody. But why --

Mr. Bowen. I can't hire a hundred people based on a maybe.

Mr. Carter. I am sorry?

Mr. <u>Bowen.</u> I can't hire a hundred people based on a maybe, based on a when is this going to end, who knows.

Mr. <u>Carter.</u> None of us can, whether we are in the private sector or the public sector, we can't do that. We all understand that.

Mr. <u>Bowen.</u> Okay. You don't -- you are not risking your livelihood and --

Mr. Carter. Sir, I risked my livelihood for 30 years as an independent retail

pharmacist. I never had -- I had contracts with nursing homes.

Mr. <u>Bowen.</u> Why don't you buy my -- why don't you buy my machines and hire a hundred people? I will tell you what, I will give you my machines if you want to hire a hundred people.

Mr. <u>Carter.</u> But the point is that, you are here saying, I am not going to do it unless I get a long-term contract from the government. I am just trying to get clear --

Mr. <u>Bowen.</u> Wait, wait, wait, wait, wait, wait. No, no, no, no, no, no, no. Go back to the context. The context of that was, in those emails, in, hey, here is four machines, let's -- they are here, but I can't turn them on unless it is a long-term deal. I am not just going to flip them on and have you flip them off and leave me hanging like everybody did last time.

And let me tell you what happened last time. The government sits around, doesn't buy American-made products, comes to me in a pandemic, buys millions of masks in 2010. You know what they did with those masks? They stored them for 10 years. Then they auctioned them to some knucklehead who put them on eBay and sold them for ten times what they were worth.

So not only did -- have I not seen the government in 10 years, I have got to compete with my own masks, and I have got to have thousands of phone calls for me -- to me from people who bought that 10-year-old mask of mine on eBay for \$10, ten times the price, yelling at me. And I had nothing to do with it. It is because the government waited and sold this stuff.

I have been hit from every side on this thing. We have bled for this country. We have created jobs. We put our factory in Texas when everybody else had already left the country.

So don't sit here and judge me for four machines that aren't running, that I would have to hire and fire a hundred people for. I am not going to do it.

Mr. <u>Carter.</u> Not unless you have a long-term government contract?

Ms. Eshoo. The gentleman's time has expired.

Mr. <u>Bowen.</u> How many times do we have to say this?

Ms. <u>Eshoo.</u> The chair recognizes the gentleman from California, Dr. Ruiz, for his 5 minutes of questions.

Mr. Ruiz. Thank you, Mr. Bowen, for your testimony today, and thank you for trying to sound the alarm on the issues of mask shortage and reliance on foreign manufacturing for over a decade now, before anyone had ever heard of COVID-19.

As you state in your written testimony, relying so heavily on imported masks is a national security risk, and, unfortunately, the last few months have shown us how vulnerable it leaves us during a pandemic.

You, of course, already knew that and tried to do something about it, and, unfortunately, those efforts were stifled.

If your warnings had been heeded, we would not be in this situation now where doctors and nurses cannot find the personal protective equipment that they need to protect themselves and do their job safely.

We all have heard the stories -- doctors reusing masks that are meant for single use, nurses wearing garbage bags because they are out of gowns. This is unacceptable. This is the United States of America, and our frontline health workers don't even have access to these basic supplies.

That is why I introduced the Commission on America's Medical Security Act, which would direct the National Academies of Sciences, Engineering, and Medicine to assess the

United States' dependence on foreign manufacturing for drugs and medical devices.

That bill was included in the CARES Act, which was signed into law in March.

Of course, the ultimate goal is a system that doesn't put our own access to critical supplies and equipment at risk because we are at the mercy of other countries during a pandemic when they need those supplies for their own populations. It is a health security risk that puts American lives on the line, and, therefore, it is a national security risk.

Mr. Bowen, when we get past this crisis and analyze the mistakes that were made in order to not repeat them in the future, how do we restructure a system so that we aren't caught in another preventable mask or other PPE shortage in future pandemics?

Mr. <u>Bowen.</u> I am not sure. I think we should put together a group of people that includes some of you all and the mask makers and the mask distributors, the VA and the DOD, and come up with a plan. It is not rocket science. It is just logistics, and the military is really good at logistics.

Mr. Ruiz. Great.

Mr. <u>Bowen.</u> And also I think too, just to be fair, again, I want to be fair with this, we couldn't -- this is an extraordinary situation. I make masks for MD Anderson Cancer Center and the Texas Health Resources hospitals in Fort Worth and Cook Children's Hospital. Those are my three biggest accounts. And they are using, my goodness, they are using so many more masks. It is not just 10 percent, 20 percent. It is hundreds of percent.

So could we have made sure everybody had masks? Probably not. But it would have been a lot better than it is now.

Mr. Ruiz. Well, if we would have heeded the warnings decades ago and created

them and ramped up our ability to produce them, then I believe that we could have.

There have been reports regarding the safety issue of some of the masks that have been imported in the past week and also reports about the FDA pulling approval for over 60 manufacturers in China for N95 masks after tests showed that they did not meet quality standards.

N95 masks filter out 95 percent of particles, hence their name, but some tests showed that many masks produced by Chinese manufacturers were, according to one CDC official, grossly under that number. One of the companies who had their approval removed filtered out only 24 to 35 percent of particles.

As a doctor who was in the emergency department, I am an emergency physician, during the H1N1, the prospect of this is horrible. It leaves those in the front lines taking the highest risk with a false sense of security and even higher vulnerability. And while I acknowledge that the FDA eventually pulled their approvals, it wasn't done before these masks were already in circulation here in the U.S.

Can you comment on this development and outline steps we can take to protect our healthcare workers against substandard masks in the future?

Mr. <u>Bowen.</u> That is not an area of my expertise. I don't know how masks get in the country. I don't know what foreign -- I don't know how that works, so I don't have a solution for that, but it is definitely a problem.

Mr. Ruiz. Okay. Let's say the President fully and comprehensively used the Defense Production Act and worked with multiple companies in multiple industries to massively produce masks and all the ingredients needed and created a supply chain, and also created a rapid response team of all the CEOs from those different companies. Would you be willing to participate in that rapid response team to handle a surge in the

future?

Mr. <u>Bowen.</u> No. I am open to any reasonable type of thing. I am not sure if -- Mr. Ruiz. Great, thank you.

Mr. <u>Bowen.</u> The government doesn't do real well managing a lot of different things, so I am not sure if that would help.

Mr. <u>Ruiz.</u> Well, I think that is why the CEOs, as a rapid response adviser team, would be very helpful.

Thank you.

Mr. Bowen. All right.

Ms. <u>Eshoo.</u> The gentleman yields back. A pleasure to recognize the gentlewoman from Michigan, Mrs. Dingell, for her 5 minutes of questions.

Mrs. <u>Dingell.</u> Thank you, Madam Chair. And I want to say, too, I want to start out thanking our Chairwoman Eshoo and Representative Susan Brooks for their leadership in understanding the stockpile and the need for the country to be producing these. And I think we really need to be talking about the medical supply chain.

I am also going to tell you, I am a car girl, I am a manufacturing girl, and I think we need to be making a lot more in America. I think that these times have changed us. I don't think people understood supply chain when we used to talk about it.

I also think there is going to be a much stronger customer base for respirator -- I used to call them ventilators, respirators, but the N95 masks that we are talking about. I think that there is going to be a permanent need in this country, and I think we have to talk about the stockpile as we go forward.

It is not a new issue, Mr. Bowen, as you have, and my colleagues have highlighted.

And that is why we are all talking about the bills that we have got in, and I have got a

good, strong, bipartisan bill with my colleague, Congresswoman Jackie Walorski, the Medical Supplies for Pandemics Act, that would reform the Strategic National Stockpile -- I still think we need it -- to strengthen domestic production of PPE.

And I am also going to say that now you are just talking about a need for frontline doctors and nurses, but as people are going back to work there is even a broader need for PPE equipment. We are reopening factories, and the supplier community and the car manufacturers are putting stringent production, new protocols into place, and they are going to have a need as well.

So I think we are going to have to talk about what is supply and demand in this country and how do we make sure that there is enough. And it is not only in times of crisis. I think there is going to be a market there. I mean, the fact of the matter is, Ford Motor -- you may not know that -- is now producing N95 masks in my district in Flat Rock, Michigan.

You were going to say something?

Mr. <u>Bowen.</u> General Motors was kind enough to send consultants to us. They have worked with us for the last 30 days.

Mrs. Dingell. I know. So the companies are stepping up.

But I want to ask you a question. I mean, Ford has, without any Federal Government order, has produced 23 -- I can't read this number, but they have been producing a lot of these masks so far, so there is a market out there.

But I want to ask you a question. Do you have any sense of how many more N95 masks would be on the market had the Federal Government taken you up on your offer to reactivate N95 manufacturing lines in January?

Mr. <u>Bowen.</u> Well --

Mrs. <u>Dingell.</u> And can we be a little short because I have got a lot of questions.

Mr. <u>Bowen.</u> Yeah. Seven million a month.

Mrs. <u>Dingell.</u> Okay. And the Medical Supplies for Pandemics Act that Congresswoman Walorski and I have introduced would authorize funding to increase supply chain elasticity, but purchasing additional capacity for manufacturers like Prestige Ameritech for emergencies, and this situation underscores the need for future investment in the area.

But, Mr. Bowen, you talked about previously that you had ramped up production of masks and hired over 150 new workers during the 2009 H1N1 pandemic to meet the increased demand. But you have since then described this decision as a mistake.

Why? I mean, you don't think you could keep the -- I actually agree with you.

Mr. <u>Bowen.</u> No, because people stopped buying my products after the pandemic. I didn't need 150 people. We went -- our sales went down. And there was such a glut in the marketplace, my biggest customer didn't order for 7 months. So not only did sales go down, some of my customers didn't order for a long time.

Mrs. <u>Dingell.</u> But you kept the equipment, the capital equipment that you had.

I guess I am trying to figure out, how do we keep production in America. I had three hospital systems that spent just a million dollars, just a million dollars, on the plane from China to the U.S. to get these N95 masks and paid quadruple the price of what they normally pay to get the masks here.

Mr. <u>Bowen.</u> Well, if they would pay 15 or 20 percent more during peacetime, they wouldn't have to do that. Because what they have done is, the hospitals have created this problem by trying to save money and chasing these products to China.

Mrs. Dingell. Well, I think we have got to bring the supply chain back to this

country, period, so we don't have to chase them, and we have got to figure out what --

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[4:00 p.m.]

Mr. <u>Bowen.</u> But, you know, what is funny, though, is I see hospitals now, in the middle of this, saying, yeah, we are going to switch back to American, but only 25, 30 percent. They still want to buy China products. So it is not going to all come back, because people aren't going to pay for it.

Mrs. <u>Dingell.</u> Thank you, Madam Chair.

Ms. <u>Eshoo.</u> The gentlewoman yields back. And now I would like to -- there isn't anyone on the minority side, right? Okay. The gentlewoman from New Hampshire, Ms. Kuster, for her 5 minutes of questions is recognized.

Ms. <u>Kuster.</u> Thank you, Mr. Bowen. And thank you for being with us, we appreciate it.

This here is a homemade mask, which is what people in my State of New Hampshire have had to do because we couldn't get the masks. And we tried in a bipartisan way. We have a Federal delegation that is Democrat, we have a governor who is Republican. We all scrambled behind the scenes. And eventually we were told, because we weren't a hot spot, we are a small State, we are a rural State, but we have plenty of COVID-19, and we couldn't get it.

And so luckily, eventually, our entrepreneurs, like yourself, stepped up. You may know Dean Kamen. He took two flights to China and came back with all the equipment, the supplies, the masks.

And so we need to understand how we got here and why nobody was listening to you about the production of masks here in America.

I want to just quickly revisit your exchange with Mr. Carter, because I don't think it is outrageous that you would be looking for a contract with a price knowing that that you would have a market. We do that in the Department of Defense all the time. How many tank manufacturers do you expect make a tank not knowing whether the government was going to buy it? Right?

Mr. Bowen. Yeah.

Ms. <u>Kuster.</u> I mean that is where we are, right? We need your product to protect our people, to protect the American people.

And my colleague Mrs. Dingell is absolutely correct. Yes, it is the frontline workers, and I every night am thinking of sleepless nights of people going home who have been exposed all day long and they are going home to their children because they didn't have the equipment that they needed. We wouldn't send our troops into harm's way and we are sending our healthcare providers into harm's way.

So just walk me through, if you will, what is it when you warned of the mask shortage, what did you think? You said the U.S. mask supply is at imminent risk. Walk me through what you were trying to convey.

Mr. <u>Bowen.</u> What I was trying to convey to Dr. Bright was that China was in the process of cutting the mask supply and that China supplies about half of the mask supply. The mask supply was already tight. So imagine half of it going away.

Now, here is what I didn't say, Mexico makes the other half. If Mexico gets in really big trouble, we might not get that supply, too. Had China not been able to get their supply or their disease under control and Mexico been in trouble, the entire U.S. mask supply would have been cut off. We dodged a bullet by just having part of it cut off.

Ms. <u>Kuster.</u> Are you familiar in the Department of Defense with the made in America and why we do that?

Mr. <u>Bowen.</u> I sent Mr. Trump a letter in 2017. I sent it to everybody in his staff. And it said, please -- I can give you the letter -- it said, please, make the DOD and VA -- or make the DOD use the Berry amendment. Masks are covered under the Berry amendment. We spent thousands and thousands of dollars with a government type attorney who made a case that masks should be under the Berry amendment because they are clothing and the Berry amendment handles military clothing and they shot it down. And then I didn't get any response from the Trump administration.

But I also wrote the Obama administration 20 letters and they sent me a form letter back. So this is everybody, this is everybody. I am not throwing any administration under the bus. This is everybody.

Ms. <u>Kuster.</u> You feel disrespected, though, in the process. And you were trying to protect the American people.

Mr. <u>Bowen.</u> No, no, no, no. What is funny is I get really mad about this, and I tend to pop off and I am sorry. I didn't used to be like this. Let me say this --

Ms. Kuster. You are frustrated.

Mr. Bowen. I didn't use to swear. I swear now, I didn't use to swear before.

Ms. <u>Kuster.</u> We are all frustrated. Let me tell you, I have let lose a few words that my mother would be shocked by. Because people are hurting, right? We can't protect ourselves.

What is your most fundamental -- are you a parent?

Mr. <u>Bowen.</u> I have five children, four living. My oldest son died of the same thing that Mr. Biden's son died of. And I have 16 grandchildren.

Ms. <u>Kuster.</u> And every night you go to bed, you would do anything to protect them. And that is the position we are in, we are trying to protect the American people. We are trying to protect our own families. And I wish you had been listened to.

Mr. <u>Bowen.</u> Let me say this, I am get 500 to 1,000 emails a day. I am getting emails from people, not businesses, I am getting emails from moms, I am getting emails from old people, please send me masks. And I --

Ms. Kuster. You make a product that can protect people.

Mr. <u>Bowen.</u> I can't help these -- I can't help all these people. And what is so frustrating, because I said this for years, I have got every email I have ever sent all these people. And I have said for years you can't, we can't wait until the pandemic happens before we do something about it is and time to fix it. We had 13 freakin' years to fix it. And that is the travesty.

But, again, the thing that I couldn't figure out is why nobody hardly would listen. It was universal. It was like, whew.

Ms. <u>Kuster.</u> Well, I will just close by saying this: Note to self, don't eliminate the Office of Pandemic Preparedness.

So thank you for being here with us today.

And I yield back.

Mr. Bowen. My pleasure.

Ms. Eshoo. The gentlewoman yields back.

Well, this concludes our second panel. I want to thank you again, Mr. Bowen, not only for coming here today, flying across the country, all the complications that are a part of that, so many flights canceled.

When I spoke to you on the phone and urged you to actually come to Washington,

you said, why? And I said, because I think you are a patriot. You have been on this for more than a decade. And I think you have more than proven that today, to every single Member that is here.

Your story and your tenacity about a commodity that is a part of our national security, I wish people had listened to. But now it is our job to listen to you and to make sure that your crusade can essentially come to an end. You shouldn't have to spend another 10, 15 years knocking on doors.

So your testimony I think has really moved the needle. And you should -- I hope that you will go home feeling gratified. You will be totally satisfied when we really get this done. But I think that your testimony has been -- you are a truth teller, totally unvarnished and refreshing, I might say.

We listen to a lot of witnesses here and there are all kinds of styles and that, but yours is a special form of truth telling, it is refreshing, and it is filled with the kind of content for us to not only understand, but that we take it and we run with it.

I started out the hearing today by saying I never thought that I would chair a hearing that is really so sad. And the backdrop of all of this are 80,000 souls that have been lost, that we are not meeting the needs of the American people in this crisis.

When it comes to what you make we can't even keep up with and make sure that doctors, nurses, healthcare workers have the supplies, the critical supplies that they need. It is shameful in our country.

So we are very grateful to you for coming.

Mr. <u>Bowen.</u> Thank you.

Ms. Eshoo. And we want you to stay healthy. We need you.

And Members will be able to submit, they all know that they can submit

questions. And pursuant to the committee rules, they have 10 business days to submit additional questions for the record to be answered by the witness, in this case yourself.

And also again we ask you to respond promptly to any such request.

So thank you again.

And I have just a little bit of housekeeping here. I request unanimous consent to enter the following documents into the record.

Mr. <u>Griffith.</u> Madam Chair, unless it is absolutely required, I will waive that reading of the list, if that is all right. And it is my understanding there are some documents that we have had a hard time getting to you, and if we could ask that they be placed in the record without objection as well with the understanding that you have to take a look at it to make sure it is appropriate.

Ms. <u>Eshoo.</u> Exactly. I reserve the right for the majority to review them, and having done so, then place them in the record. And I appreciate the gentleman agreeing or waiving the unanimous consent request.

Ms. <u>Kuster.</u> Madam Chair?

Ms. Eshoo. Yes. You are recognized.

Ms. <u>Kuster.</u> Could I just ask for the record that Mr. Bowen's letter that he made reference to be entered into the record?

Ms. Eshoo. And what letter is that?

Ms. <u>Kuster.</u> You referenced a letter that you had sent to the administration about the making of masks.

Mr. <u>Bowen.</u> Yes. I can send the letters I sent to both the Obama administration and the Trump administration.

Ms. Eshoo. If you can get that to us, Mr. Bowen, then both sides can review.

And with the approval, the agreement of both sides, we can place them in the record.

Mr. <u>Griffith.</u> Yes, ma'am.

Mr. <u>Bowen.</u> Would you like the letters I sent to Secretary Mattis and other people as well?

Ms. <u>Eshoo.</u> Whatever you want to give us, we will review. Be happy to.

Mr. <u>Griffith.</u> And if I might, Madam Chair, I know it was probably said in frustration, but as I indicated to you that I had a number of companies that had gotten back into the business. And one of those, Integrated Textile Solutions, says they will take the machines if you really want to get rid of them. Just letting you know.

Mr. Bowen. We will work something out.

Mr. Griffith. I will put you all together and y'all can figure it out.

Mr. Bowen. We will work something out.

[The information follows:]

***** COMMITTEE INSERT ******

Ms. <u>Eshoo.</u> On behalf of all of the Members, we want to thank the committee staffs on both sides. This is our new way of operating. And as everyone makes the adjustments, you are doing the hard work so that we can make the adjustment to make sure that the directives of the Capitol physician's office has put out.

And I can't thank you enough. I mean, you have been -- I have been watching you. I even said to Mike, you don't have gloves on.

So thank you to all of you. I salute you.

And again, Mr. Bowen, thank you.

To the rest of the guests in the room, thank you.

Now maybe some of us are going to go off and have breakfast and lunch combined, something like that. I think we kind of earned our keep today with 4 -- 6 hours of well spent time on behalf of the people of our country.

So with that, the Health Subcommittee is adjourned.

Mr. <u>Bowen.</u> Thank you for the invitation.

[Whereupon, at 4:13 p.m., the subcommittee was adjourned.]