# EXAMINING EMERGENT BIOSOLUTIONS' FAILURE TO PROTECT PUBLIC HEALTH AND PUBLIC FUNDS

## HEARING

BEFORE THE

SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS

OF THE

COMMITTEE ON OVERSIGHT AND REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTEENTH CONGRESS

FIRST SESSION

MAY 19, 2021

**Serial No. 117–23**

Printed for the use of the Committee on Oversight and Reform

Available on: *govinfo.gov, oversight.house.gov* or *docs.house.gov*

U.S. GOVERNMENT PUBLISHING OFFICE

44–686 PDF WASHINGTON : 2021

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*Documents entered into the record during this hearing are listed below.*

* Article regarding the President's ban on intellectual property in China; submitted by Rep. Scalise.

*Documents are available at: docs.house.gov.*

# EXAMINING EMERGENT BIOSOLUTIONS' FAILURE TO PROTECT PUBLIC HEALTH AND PUBLIC FUNDS

**Wednesday, May 19, 2021**

HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND REFORM
SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS
*Washington, D.C.*

The subcommittee met, pursuant to notice, at 10:40 a.m., 2154 Rayburn House Office Building, Hon. James E. Clyburn (chairman of the subcommittee) presiding.

Present: Representatives Clyburn, Waters, Maloney, Velázquez , Foster, Raskin, Krishnamoorthi, Scalise, Jordan, Green, Malliotakis, and Miller-Meeks.

Chairman CLYBURN. Good morning.

The committee will come to order.

Without objection, the chair is authorized to declare a recess of the committee at any time. I now recognize myself for an opening statement.

I want to begin by thanking our members and today's witnesses for joining us today. The coronavirus pandemic has brought out the best in many of our citizens. We have been inspired by the doctors, nurses, and other frontline workers who have put their own lives on the line to help others, and by the scientists who created coronavirus vaccines in record time.

At the same time, others have sought to profit from the pandemic, put lives at risk, and violate the public trust. That is why we are here today. Last year, the Trump administration awarded Emergent BioSolutions nearly $650 million in taxpayer funds to manufacture coronavirus vaccines that were then being developed by companies like Johnson & Johnson and AstraZeneca. But nearly a year later, Emergent has destroyed millions of vaccines due to contamination, and millions more are being held back for testing, to ensure that they can be used, all due to Emergent's failure to properly maintain its facilities, adequately train its staff, and ensure that proper protocols were followed.

I want to be clear. This hearing is not about questioning the safety or efficacy of vaccines that have been authorized for use. The vaccines available to the public are safe and effective, and I encourage everyone who has not been vaccinated to do so as soon as you can. Emergent's failures are disappointing precisely because these vaccines are so effective. Because the company was unable to de-

liver, the vaccinations to millions of people around the world have been delayed, putting their lives at needless risk.

This morning the Select Subcommittee released its staff memorandum detailing several concerning findings from our investigation into Emergent. The documents released today shed light on the multiple warnings Emergent received last year regarding serious manufacturing problems at its plant, including a new report regarding a June 2020 inspection, which found that Emergent had an inadequate contamination control strategy at its vaccine production facility. The documents also revealed that after failing to heed these warnings and contaminating millions of doses of critically needed vaccines, Emergent determined that its executives' performance merited millions of dollars in bonuses.

These documents provide insight into the dysfunction at Emergent that caused so many life-saving vaccines to be ruined, but also leave us with many questions. We have questions about how these vaccines came to be ruined, not just this past February, when Emergent destroyed up to 15 million doses of the Johnson & Johnson vaccine, but in at least three other incidents last year.

We have questions about why Emergent failed to take action to fix the manufacturing problems plaguing its plant, even after the company was warned that its poor practices led to a very real risk of contamination.

We have questions about why the Trump administration invested so much in Emergent in May 2020, particularly when an FDA inspection conducted just a month earlier raised serious red flags.

Former President Trump's own Assistant Secretary for Preparedness and Response, has admitted that he knew that the decision to entrust hundreds of millions of dollars with Emergent was a risk. Yet he did so anyway. Documents released today raise new questions about what exactly Emergent was being paid to do.

We have questions about whether Emergent was favored for these lucrative Federal contracts because of its close relationship with the Trump administration appointee who was responsible for them.

We have questions about how the company's actions, for several years leading up to the pandemic, squeezed budgets and deprived our country of critical supplies, inhibiting our ability to respond when the virus reached American shores.

We have questions about the Emergent executives, whether they earned the millions of dollars in bonuses they were awarded while all of this was happening.

I look forward to hearing from today's witnesses so that the American people can start to get answers. But today's hearing is only the beginning. The Select Subcommittee, along with the Committee on Oversight and Reform, has opened an investigation into Emergent and its troubling practices. I would like to thank Chairwoman Maloney for joining me in this important endeavor.

I now recognize her for a two-minute statement.

Ms. MALONEY. Thank you, Chairman Clyburn. Thank you for calling this important hearing and for partnering with me on this joint investigation being conducted by the Oversight Committee and Select Subcommittee on Emergent BioSolutions.

As we work to end the coronavirus pandemic, it is essential that we vaccinate as many people as possible in this country while supporting a global vaccination effort. To do so, we need our contracting partners in the private sector to fulfill their commitments. I have concerns, serious concerns that Emergent executives, instead of fulfilling their commitments to the American people, appear to have wasted taxpayer dollars while lining their own pockets.

In April 2020, the FDA raised concerns about Emergent's Bayside facility in Baltimore, including problems with quality control standards, inadequate training, and risk of contamination. Just one month later, disregarding all the red flags, Emergent received a $628 million contract to produce coronavirus vaccines. That means Emergent made a commitment to the government and the American people that it could safely manufacture these vaccines, despite the recent problems and concerns of the FDA.

Unfortunately, the company has failed to live up to that commitment. Poor lab practices at Emergent have led to millions of corona vaccines being thrown out because of contamination or suspected contamination. In other words, the company took taxpayers' money, at least $271 million so far that they have spent, but failed to deliver the crucial, life-saving coronavirus vaccines that the country needs.

But at the same time that the company was destroying millions of vaccine doses, at the direction of the FDA, its executives were cashing out. Last year, CEO Bob Kramer received $5.7 million in total compensation, an increase of 51 percent from 2019. He has yet to have given this country one vaccine, yet they have taken $5.7 million, as payment over 275 in contracts, and Executive Chairman Fuad El-Hibri cashed out in stock worth more than $42 million. So, as they are destroying the vaccines they are cashing out, taking stock out of the company. These stock trades raised serious questions about why top executives were selling shares when they knew about serious problems at Emergent's Baltimore plant, but the public didn't know about it, and I repeat, they hadn't produced one single vaccine.

I am glad that Mr. Kramer and Mr. El-Hibri have agreed to appear today. Thank you very much. I would also like to point out that although some of the documents we requested have been produced, many, many more are outstanding. It is imperative that Mr. Kramer and Mr. El-Hibri commit to producing all responsive documents in a timely manner. I also expect, and I am sure my colleagues join me in this request, that both witnesses commit to return to testify once again that document production is complete and our committees have completed our investigation. It is very difficult to conduct oversight when the documents we request have not been received. So again, respectfully I request, for the committee, for the government, for the taxpayers, that the documents we requested are produced. At least produce the documents.

I thank you very much for being here, I thank the chairman, I thank my colleagues. I yield back.

Chairman CLYBURN. Thank you. I now recognized the distinguished ranking member, Mr. Scalise, for his opening remarks, and

to recognize an additional member of the minority, for a two-minute statement. Mr. Scalise.

Mr. SCALISE. Thank you, Mr. Chairman, and I want to thank you for holding today's hearing. Each of us had felt the renewed freedom, and we enjoy seeing the smiles of our friends and neighbors again this past week as mask mandates have been dropped. Masks are flying off the faces of Americans faster than liberals in Washington spend a trillion dollars. That is a great thing to see.

Those of us on the Select Subcommittee on the Coronavirus Crisis have a duty and a responsibility to help educate our colleagues, our constituents, the media, and leaders in education and business about how we got here. We have had a spirited debate about the effectiveness of lockdowns. Let's set that aside for today, and God willing, leave that debate in the rear-view mirror, where history will ultimately pass their judgment.

But every one of us on this subcommittee should look our colleagues in the eye and say that there is bipartisan agreement on this subcommittee that it was the vaccine that ended this pandemic. So,how did we get to this point where America created the fastest vaccine in human history and produced, manufactured, and distributed enough vaccine to give a shot to every American who wants one?

The story begins over 30 years ago, when the U.S. Trade Representative began negotiating international trade agreements in earnest. On a bipartisan basis for three decades, USTR made protections of U.S. intellectual property a cornerstone of those agreements. Trade agreements have proved controversial from time to time, but what has never been controversial was that if American ingenuity could flourish and is protected, that America can compete and win. And over that period, American pharmaceutical companies led the world in both research and development and the introduction of new, life-saving drugs.

About 25 years ago, after Republicans took back the majority for the first time since 1955, Congress decided to make a major push on biomedical research. The Republican Congress worked with then President Bill Clinton to double the size of the National Institutes of Health. During the administration of George W. Bush, the Republican Congress made yet another major investment in NIH, with strong bipartisan support.

During the Bush Administration, the Federal Government began to take seriously the threat of bioterrorism and pandemic response. The Executive branch began working with Emergent on producing anthrax and smallpox vaccines. It takes time and expertise and partnerships to have the infrastructure in place to respond effectively. When H1N1 hit during the Obama-Biden administration, America was not ready. White House Chief of Staff Ron Klein actually acknowledged as much, saying that we just got lucky. Well, hoping to get lucky is not a smart strategy.

But we did keep at it. We invested in BARDA. The Executive branch's relationship with Emergent continued throughout the Obama years, and they continued to develop expertise and infrastructure on some highly sophisticated manufacturing techniques and technologies. President Bush launched PEPFAR, a public-private partnership to save Africa from the AIDS epidemic. A key pil-

lar in that was working with U.S. pharmaceutical companies on developing key drugs and protecting their intellectual property.

And then came Fred Upton and Diana DeGette, and their bipartisan leadership on the 21st Century Cures Act. That was one of my proudest efforts during my tenure as majority whip, to see that bill signed into law. We doubled NIH yet again, and just as importantly, we established the Emergency Use Authorization process, upon which this vaccine would be approved, a provision that, by the way, is saving millions of lives.

In January 2020, China lied to the world, and the lies of the Communist Party of China caused COVID–19 to spread throughout the globe, igniting the worst pandemic we have seen in 100 years. What we can say now, as far as finding a vaccine and a way out of the pandemic, is that America led the world. President Trump's Operation Warp Speed built on 30 years of smart policy. It was focused on protecting IP, investing in biomedical research, and investing in public-private partnerships on critical manufacturing infrastructure.

President Trump's leadership on Operation Warp Speed was critical. Importantly, OWS leveraged work going back over two administrations, Republican and Democrat, to partner with companies like Emergent to begin the manufacturing process before the vaccines were even approved. That decision proved to be a gamechanger. It is why we could get so many shots in the arms of Americans so quickly after getting the Emergency Use Authorization.

Mr. Chairman, President Bush—President Biden, has now put at risk a key pillar of this strategy, the protection of United States intellectual property. You have seen President Biden talking about actually giving away America's intellectual property. This is something that would be a cave into the special interests in Washington, some progressives who don't believe that America should be the ones who own our own intellectual property.

For years Republicans and Democrats alike were criticizing China's theft of American intellectual property. Today you have got the Biden administration talking about giving away our intellectual property to China, for nothing. How outrageous would that be?

Imagine where we are because of American ingenuity, which is now at risk. Stripping innovators of their constitutionally protected patents will undermine that very innovation. It will weaken our international competitiveness, and only help Communist China, the country that spread this pandemic. It would force the American developers of COVID–19 vaccines and therapeutics to relinquish their intellectual property rights to these medicines.

But it will likely take manufacturers years to build the facilities. If we give this intellectual property away, which we strongly urge the Biden administration not to do, but if that were to happen, it is not like tomorrow they just start making those vaccines that are being made in America. What is being made in America is using American infrastructure that was built over years, and, in fact, over multiple administrations, Republican and Democrat. That ability does not exist today in China. If we give away the technology, we lose the technology, but China would not be able to safely and effectively mass produce those drugs for years. So,make no mistake. This is not about helping the world get COVID vaccines

quicker. It is about undermining American ingenuity and intellectual property.

Today's hearing underscores that critical point. The Federal Government has worked with Emergent over Democrat and Republican administrations on complicated, sensitive biomedical manufacturing infrastructure, and yet the majority feels they need to undermine confidence in the drugs that they produce. Does anyone believe that handing over U.S. intellectual property to a startup, in a far less developed country is going to quickly yield actual safe and effective shots in the arm? Of course it will not.

President Biden is destroying 30 years of successful bipartisan policy, and for what? His plan won't even work. Why don't we protect American intellectual property? Contract with U.S. manufacturers, and help distribute the vaccine to countries who are in need. It is a quicker and a smarter strategy. There would be more shots given and we wouldn't have to kneecap our future pandemic responses to do it. Instead of putting shots in arms, the Biden administration is putting U.S. IP in China's hands. That is insane.

With that, Mr. Chairman, I yield two minutes to the gentlelady from Iowa.

Mrs. MILLER-MEEKS. Mr. Chair, I have a parliamentary inquiry first.

Chairman CLYBURN. The gentlelady is recognized.

Mrs. MILLER-MEEKS. Thank you. My parliamentary inquiry, Mr. Chairman, recent CDC guidelines state, quote, "Fully vaccinated people can resume activities without wearing a mask or physically distancing," end quote. It clarifies further fully vaccinated people, quote, "can resume activities they did prior to the pandemic," end quote. It says vaccinated people do not need to wear a mask inside. This is all regardless of the vaccination status of people around you.

I wholeheartedly agree with the chairman that these vaccines are extraordinarily effective, but contrary to the science, the House Attending Physician is mandating mask-wearing for vaccinated members.

Mr. Speaker, why isn't the committee charged with upholding public health CDC guidelines on masks?

Chairman CLYBURN. My understanding is that this committee is being governed by the recommendations of the Attending Physician. Now I don't believe that that is a valid parliamentary inquiry, and I will recognize whoever is to be recognized for their two-minute statement.

Mrs. MILLER-MEEKS. Thank you, Mr. Chair.

On May 11, committee Republicans sent a letter to the CDC about the apparent influence of the American Federation of Teachers on official government documents. We have yet to receive a response. The AFT is not a medical group. It is not a scientific group. Yet it is providing verbatim edits to scientific and medical guidance, at the CDC's request.

Chairman Clyburn and the House Democrats spent the better part of a year investigating alleged influence at the CDC, but remain silent on these egregious reports. This is influenced by political operatives that are both unelected and unaffiliated with the

Federal Government. As one of the two medical experts on this committee, this is appalling.

President Biden promised his administration would follow science and truth. Director Walensky said the guidance was free from medical meddling. A paper trail shows this to be patently false. Biden's Secretary of Education said, quote, "In-person learning offers our young people the best opportunity," end quote. Why not listen to him?

The Democrats and the teachers' union kept schools closed, and now not only has a generation of young children been robbed of a year of education, but mental health problems are up 31 percent, drug use and addiction resulting in overdose have exploded, and children as young as 9 have committed suicide, all traced back to the shuttering of schools. Now we know who is responsible, the teachers' union. Union involvement in the drafting and editing of scientific guidance is the very definition of political meddling. It is unclear how many children were locked out of school because of the union's selfishness, and even today, summer camps don't have guidance from the CDC on reopening without masks. Do they need to hire the AFT?

The lives of American children must be governed by medical science and not political science.

Thank you, Mr. Chair. I yield my time.

Chairman CLYBURN.

[Inaudible] and Chief Executive Officer of Emergent BioSolutions. He joined Emergent in 1999 as Chief Financial Officer, and held a variety of executive leadership roles until becoming CEO in 2019. He is a member of Emergent's board of directors.

Mr. Fuad El-Hibri is the Executive Chairman of Emergent's Board of Directors. He founded Emergent in 1998, and served as Chief Executive Officer from the company's founding in 2012.

Will the witnesses please raise their right hands so I may swear them in. Do you affirm or swear that the testimony you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

[Witnesses are sworn.]

Chairman CLYBURN. Thank you. Let the record show that the witnesses answered in the affirmative.

Without objection, your written statements will be made part of the record. Mr. Kramer, you are now recognized for five minutes for your opening statement.

**STATEMENT OF ROBERT G. KRAMER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, EMERGENT BIOSOLUTIONS, INC.**

Mr. KRAMER. Chairman Clyburn, Chairwoman Maloney, Ranking Member Scalise, and members of the subcommittee, my name is Bob Kramer. I am the CEO of Emergent BioSolutions. Thank you for the opportunity to appear today to discuss Emergent's role in the COVID–19 pandemic response.

We have worked around the clock at every level in our company since we were called upon to be a critical manufacturer of COVID–19 vaccine. I can assure you that no one is more disappointed than we are that we had to suspend our 24/7 manufacturing of new vaccine. As CEO, I take full responsibility for that.

At Emergent, we focus on public health threats that pose an extraordinary danger to the Nation, such as bioterror weapons. Currently, our portfolio is comprised of vaccines and therapies for anthrax, smallpox, typhoid fever, cholera, and botulism. We are also part of the fight against the opioid crisis, with our Narcan nasal spray product.

After the 2009 H1N1 pandemic, BARDA recognized that the United States lacked sufficient domestic capability to rapidly manufacture vaccines in quantities necessary to meet the demands of a pandemic emergency. This prompted BARDA to fund three Centers for Innovation in Advanced Development and Manufacturing, or CIADM. In 2012, our Bayview operation was selected as one of those facilities. However, despite our own investment of more than $200 million, the expected pipeline of government task orders to utilize the facility persistently fell short of what was needed to reach full operating potential. As a result, by the end of 2019, Bayview had roughly 100 employees and was less than a year away from licensure.

When the COVID–19 pandemic began, Emergent, the U.S. Government, and our other partners recognized that while Bayview was not yet fully staffed or operating at scale, the facility's unique attributes could be used to support the challenge of producing mass amounts of vaccine.

In April 2020, Emergent agreed to manufacture a drug substance for the J&J COVID–19 vaccine candidate at Bayview. In late May, the government issued a task order, under the CIADM contract, requiring us to reserve additional Bayview capacity, which we were later directed to release to AstraZeneca.

Ramping up production of two novel vaccines on a very large scale in the same facility is unprecedented, but the government decided that given the critical need, Emergent should manufacture both drug substances simultaneously, and we moved with extraordinary speed to scale up the new technology. We began manufacturing of the AZ bulk drug substance in August 2020, and did the same for J&J in November.

However, in March 2021, a single batch of J&J's COVID–19 vaccine candidate failed routine quality control testing. We immediately initiated an investigation which determined that the bioreactor material used for the J&J program was in the vicinity of material being disposed of from the AstraZeneca suite. Detailed testing was also conducted on other batches in process, and the presence of AstraZeneca virus was not detected.

We have implemented an array of corrective steps. Critically, we have removed the AstraZeneca vaccine candidate from Bayview, which is now dedicated only to the J&J vaccine. J&J has been onsite with us throughout the pandemic, and they are now providing 24/7 oversight of all production areas, change control, qualifications, and process items.

I understand that we are here today to answer for the contamination incident, and I apologize for the failure of our controls, and I give you my personal assurance that I will take every step that is needed to resume production safely.

At the same time, I do want to take this opportunity to let you know that many Emergent employees, from frontline workers to

engineers and managers, have been working around the clock, putting much else in their lives on hold, sometimes at considerable personal sacrifice amid the pandemic, as they have sought to ensure that we all have access to COVID–19 vaccine. They have been the true heroes here, and I am deeply appreciative of their dedication, their hard work, and their sacrifice.

Thank you, and I look forward to your questions.

Chairman CLYBURN. Thank you very much, Mr. Kramer. We will now turn to Mr. El-Hibri. You are now recognized, Mr. El-Hibri, for five minutes.

**STATEMENT OF FUAD EL-HIBRI, EXECUTIVE CHAIRMAN OF THE BOARD OF DIRECTORS, EMERGENT BIOSOLUTIONS, INC.**

Mr. EL-HIBRI. Chairman Clyburn, Chairwoman Maloney, and Ranking Member Scalise, and members of the subcommittee, my name is Fuad El-Hibri and I am the Executive Chairman of Emergent BioSolutions. Thank you for the opportunity to appear before you today and answer questions regarding Emergent's role in responding to the COVID–19 pandemic.

Emergent started in 1998, as a small company that acquired the rights to a laboratory and manufacturing facility. The site's primary function was to produce anthrax vaccine for the Department of Defense. The manufacturing capacity at that time was only a fraction of what the U.S. military required. At the time of the acquisition, the facility was subject to an FDA notice of intent to revoke its license.

I served as the President and Chief Executive Officer of Emergent from its inception until 2012. Since that time, I have been Executive Chairman of the board of directors, which means I am responsible for board leadership, governance-related external outreach, and advising the management team on strategic decisions, rather than day-to-day management.

Emergent handles some of the most challenging biological materials in its manufacturing processes, including anthrax bacteria and live virus strains. Since its founding, we have strived to manufacture at the highest quality. The board takes that responsibility very seriously. On behalf of the board, I would like to assure the subcommittee and the American people that we understand the importance of responding to the COVID–19 pandemic.

As you are aware, we recently had a cross-contamination event with one lot of vaccine drug substance at our Bayview facility in Baltimore, Maryland. Manufacturing drug substance for two viral products in one facility, on a massive scale, while incorporating new manufacturing technology into the facility is a challenge at any time, even more so in the midst of a public health emergency.

Let me be clear. The cross-contamination incident is unacceptable, period. Mr. Kramer will testify regarding the specific actions that the company is taking to remedy the situation.

At the board level, we have expanded our oversight. In the last six weeks, in addition to our regular meetings, the board has met six times to oversee management's progress. At our last board meeting, the board authorized the creation of a special committee charged with manufacturing and quality oversight.

In addition, in consultation with the board, Mr. Kramer has recently changed the reporting structure for the quality organization. Mr. Kramer has also changed management oversight for the Bayview facility.

I want to assure the subcommittee that Emergent is committed to addressing all quality and manufacturing issues at the Bayview facility with diligence, thoroughness, and urgency, so that Johnson & Johnson can deliver safe and effective vaccines to the American people and the world.

I would also like to address the suggestion that my personal relationship with Dr. Robert Kadlec influenced the award of government contracts to Emergent. This is simply not true. Dr. Kadlec has had a distinguished career in the U.S. Government, including the Air Force and senior positions in Congress and the Executive branch, working on biodefense issues. During his time outside of government, he was a valued consultant to our company and others. Emergent's contracts with the U.S. Government have all been subject to standard government contracting procedures, overseen by independent career government contracting officers.

To conclude, I would like to emphasize that Emergent takes very seriously its role as a reliable supplier of medical countermeasures, vaccines, and therapeutics for public health threats to the U.S. Government and patients. We remain very focused on addressing the manufacturing challenges at the Bayview facility, and the board's top priority is ensuring that management takes all corrective actions required to resume production.

Thank you for the opportunity to appear today. I look forward to answering your questions.

Chairman CLYBURN. Thank you very much, Mr. El-Hibri. Each member will now have five minutes for questions. The chair now recognizes himself for five minutes.

Mr. Kramer, in March, we learned that Emergent's Baltimore plant was forced to destroy millions of coronavirus vaccines over the last six months due to suspected contamination. Mr. Kramer, exactly how many doses of the Johnson & Johnson vaccine and AstraZeneca vaccine were destroyed due to contamination at your plant, and how many others have not been shipped because of ongoing safety testing?

Mr. KRAMER. So, Chairman Clyburn, just to be clear, our work for J&J and for AstraZeneca is to manufacture the bulk drug substance for both of those candidates. I can't specifically comment on the number of doses. What I can comment on is the incident that occurred in March resulted in the loss of one batch. It was a viral contamination. That was what our root cause investigation determined. And the equivalent number of doses associated with that one batch was about 15 million doses.

Chairman CLYBURN. So, for both AstraZeneca and Johnson & Johnson, the total was 15 million.

Mr. KRAMER. Chairman Clyburn, I was just speaking the Johnson & Johnson product, not the AstraZeneca product. So, I think it is important to understand that when we began this work back last year, in April and May, we were challenged, along with our network of partners, AstraZeneca, J&J, and the U.S. Government, and BARDA, to very quickly tech transfer in these two candidates,

scale them up, and be in a position to make tens of millions, if not hundreds of millions of vaccines. That process typically takes one to two years, and we were being asked to do that in a period of months.

The early stages of the manufacturing, particularly of the AstraZeneca product, resulted in a number of lost batches, because the startup was occurring so very quickly and we were really working at unprecedented pace.

Later, in 2020, once the cadence and the process was established and locked down and validated, we were operating in areas with a much greater success rate. I can't give you an exact number of doses that were lost of the AstraZeneca product. I can simply comment that we did lose a number of production runs early in the scaling up of the manufacturing process, because of the pace that we were responding to, along with BARDA, along with AstraZeneca, to be in a position to respond to the pandemic very, very quickly.

Chairman CLYBURN. Well, do you think you might be able to get that number to us, at a later date?

Mr. KRAMER. Yes, Mr. Chairman. I would be glad to do that.

Chairman CLYBURN. Well, thank you very much. Now I want you to understand, we are not second-guessing anything here. This committee is really trying to find some accountability for what we consider to be some egregious failures. So, let me ask this. How many doses of each of these have been shipped abroad, and of those, how many are currently being held by foreign authorities for testing to confirm whether or not they are safe to use?

Mr. KRAMER. So, Chairman Clyburn, we manufacture the drug substance for both AstraZeneca and J&J, and after our production is complete we ship that product to AstraZeneca and to J&J. They, in turn, do the—or through other contractors of theirs—do the actual final fill and finish and labeling and packaging, and placing of the vaccine in the final vials that you are used to seeing when you are immunized. So, I can't tell you exactly the number of doses that are in their possession, because we ship them drug substance in large volumes. They, in turn, put it in the final container, and they determine where that product is shipped. I can only describe to you the number of drug substance batches that we have manufactured and supplied to both AstraZeneca and J&J.

Chairman CLYBURN. So, you can get that number to me also?

Mr. KRAMER. Yes, sir.

Chairman CLYBURN. Thank you. I now yield to the ranking member for five minutes.

Mr. SCALISE. Thank you, Mr. Chairman. Mr. Kramer, I first want to ask about Operation Warp Speed. What is your view on how that worked? Did that work the way it was intended to open the door so that we could get multiple vaccinations moved through the FDA process quickly, in record time, in a safe and effective manner?

Mr. KRAMER. So, Ranking Member Scalise, I think Operation Warp Speed had a lot of very positive attributes and principles, one of which clearly is this notion of strong public-private partnerships, and second, the idea that in order to quickly develop and scale and make available hundreds of millions of vaccine doses, it was really

important to do, in parallel, things like clinical development and manufacturing development. Typically you wouldn't do those two activities at the same time, but in order to ensure that if and when any of those vaccine candidates would be showing clinical benefit, then we would have a current amount of inventory to be made available.

I think it is important to note that a year ago this time we were facing the pandemic without any vaccine available to protect the public, and our government and industry partners got together and formed an incredibly powerful network of public-private partnerships in order to rapidly advance the development and the scale-up of multiple vaccine candidates, not knowing which, if any of those, would be shown to have clinical benefit yet available today. I think it is quite remarkable that a year later we have three vaccines that are Emergency Use Authorization approved by the FDA, with hundreds of millions of Americans being protected from those vaccines.

Mr. SCALISE. Well, thank you, and clearly President Trump deserves credit for getting government red tape out of the way and just focusing on letting these great drug companies do the work that they do in coming up with cures. I mean, here you had a virus that was not even known to the world, and less than a year later we have got multiple vaccines that have moved their way through the FDA process, and clearly the FDA process is involved in how your facility runs.

How many facilities like yours are there in the United States, Mr. Kramer?

Mr. KRAMER. Ranking Member Scalise, in 2012, BARDA established three different CIADM facilities, ours being one of them. There is also one associated with Texas A&M University and one in North Carolina. To my knowledge, when BARDA made the decision to kind of tap us on the shoulder and access our facility to support these two vaccine candidates, the other two may not have been ready to do the work that we were asked to do.

Mr. SCALISE. So, this happened under the Obama-Biden administration that you all started getting into this line of business?

Mr. KRAMER. That is correct.

Mr. SCALISE. So, the FDA process that we are talking about on the cross-contamination, was it you all who identified this? Was it the FDA? Were all the FDA processes followed, or has that been resolved?

Mr. KRAMER. So, the contamination event was identified through our quality control procedures and checks and balances. When we were informed and made aware that the contamination occurred, as we always do we opened up an investigation to determine the root cause of that contamination event. That information was shared with the FDA as soon as the investigational report was completed in early April.

Mr. SCALISE. So, you followed those FDA processes. Did any of the contaminated doses get out of your facility? Were any put in the arms of people, or was this an internal discovery that stayed internal?

Mr. KRAMER. Importantly, Ranking Member Scalise, our internal quality control procedures identified the out of specification and the

contamination. None of that material left our control. The production lot was quarantined, set aside, and never left our facility.

Mr. SCALISE. And I know we are going to have a second round of questions. I do want to get into this, though. I understand there are some batches that were made that were not contaminated but that the FDA has not released yet. Is that the case, and if so, how many doses would that amount to that right now are not available to be distributed to Americans and maybe other people around the world, that the FDA hasn't released?

Mr. KRAMER. Yes, Mr. Scalise. There are a number, a significant number of doses that we manufactured. Again, we manufacture the bulk drug substance, and it has been reported in a number of the news agencies there are probably over 100 million doses of the J&J vaccine that we have manufactured that are now being evaluated by the FDA for potential release and availability to the public.

Mr. SCALISE. I am out of time but I want to get into that if there is a second round, Mr. Chairman. I yield back.

Chairman CLYBURN. Thank you very much, Mr. Scalise. I now yield to Ms. Waters for five minutes.

Ms. WATERS. Thank you very much, Mr. Chairman. I am so pleased that you are holding this hearing, because information regarding Emergent is absolutely concerning. And so I want to two representatives who are here today to try and clear up some of this information.

First of all, let me ask Mr. Kramer, or Mr. El-Hibri, how did you get this contract? It was a no-bid contract, and you referred to it as a relationship, or a joint venture between the government and you. How did you get the contract, and how much the government contribute to the contract in order for you to be ready and capable of delivery, and how much did you contribute? How much did Bayview contribute?

Mr. KRAMER. Congresswoman Waters, are you asking about the 2012 contract or the 2020 contract, if I could ask, please.

Ms. WATERS. I am talking about the one where you were awarded $27 million per month in order to be involved with production of the vaccine.

Mr. KRAMER. So, Congresswoman Waters, that was the task order that was awarded to Emergent by BARDA. In April or May 2020, they selected our facility because BARDA wanted to have immediate access to manufacturing capacity for COVID–19 vaccines——

Ms. WATERS. May I stop you for one minute, because I want to know what Mr. Robert Kadlec had to do with this contract. Now as I understand it, Robert Kadlec was a former consultant to Emergent. Is that right?

Mr. KRAMER. That is correct.

Ms. WATERS. And that he had been paid some $360,000 by Emergent before awarding the contract, but he had something to do with significant participation in your getting the contract. Is that right?

Mr. KRAMER. Congresswoman Waters, I am not aware that Dr. Kadlec was directly involved in any award of a contract, this contract to Emergent.

Ms. WATERS. Why are you not aware of it? He worked as a consultant to you. Then he went over to the administration where he

worked, you know, for the President, and he was involved in decisions about contractors, and yours in particular. Are you telling me that you did not know that?

Mr. KRAMER. Congresswoman Waters, what I am——

Ms. WATERS. You are under oath, sir.

Mr. KRAMER. Yes, ma'am. I know that. What I am——

Ms. WATERS. Are you telling me that Robert Kadlec had nothing to do with the awarding of the contract to Emergent?

Mr. KRAMER. I am not aware of his direct involvement, Congresswoman Waters, and the contract. All of our negotiations and discussions with the government were with BARDA. BARDA is the agency who awarded the contract.

Ms. WATERS. Thank you. If you are basically saying that you do not know, let the record reflect that. Thank you very much.

Now, getting this $27 million per month, were you ever paid anywhere between $20 and $27 million, even though you were not producing?

Mr. KRAMER. Congresswoman Waters, the nature of the contract was to allow the government to have access to our facility, for them to direct activity. After awarding the contract they directed us to immediately begin work with AstraZeneca to tech transfer in, or to transfer their candidate into our facility, scale up the manufacturing process, and begin the work.

Ms. WATERS. Thank you. I understand that. But were you paid $27 million per month despite the fact you were not manufacturing in some of those months?

Mr. KRAMER. I believe we were, yes.

Ms. WATERS. OK. Thank you very much. Now let me also ask you about the fact that Emergent had more than once, on several occasions, been told that your facility was not safe, that basically you had contamination problems. How many times were you warned, or told about your contamination problems?

Chairman CLYBURN. I am going to ask the gentlelady to hold that question for the next round, because her time has expired.

Ms. WATERS. Thank you. Thank you, Mr. Chairman.

Chairman CLYBURN. The chair now recognizes Mr. Jordan for five minutes.

Mr. JORDAN. Thank you, Mr. Chairman. I will have a question in the second round for Mr. Kramer, but first round here I wanted to focus on a fundamental question. Why don't Democrats on this committee want to know how the virus started? Seventeen months, 150 million cases worldwide, 600,000 Americans lost their lives. Where did this thing start? Did it jump from an animal to humans, or was it a leak from a lab, a lab in Wuhan, China? American people would probably like to know. After all, they have had their liberties assaulted for the past year.

The World Health Organization did a study and issued a report, the same World Health Organization that Republicans on this committee asked to come in front of this committee three separate times and the Democrats denied us our request. Their report said this, quote, "It was extremely unlikely that the lab leak was the cause." Just one problem with that finding—nobody believes them.

President Biden's Director of National Intelligence, Avril Haines, said this, "That is not our assessment." Secretary of State Blinken

said, "We have got real concerns about the methodology and process that went into the WHO report." Secretary of Health and Human Services Becerra, a former colleague of ours, said, quote, "We have to understand how COVID surfaced, but the Select Committee in Congress on COVID doesn't want to know."

Journalists want to know. Josh Rogin, in a Washington Post column two weeks ago, he starts his column off by quoting our colleague, Congressman Gallagher. "Understanding the cause of the pandemic and ensuring that something like it never happens again is the most important question we face." He goes on to say this: "The Republicans are taking the first steps in a long-overdue effort, but without backing from Democrats who are conspicuously absent from these efforts. The investigations will struggle." Very true. The Select Committee on the Coronavirus won't look into how coronavirus started. I find that fascinating. I find that amazing.

Nicholas Wade, former New York Times science writer, said this: "When looking at the two scenarios," he says, quote, "it is a stretch to get the pandemic to break out naturally outside of Wuhan, and then without leaving a trace to make its first appearance in Wuhan." But he says this for the lab escape scenario: "A Wuhan origin for the virus is a no-brainer. Wuhan is home to China's leading center for coronavirus research. Researchers were genetically engineering bat coronaviruses to attack human cells. They were doing so under minimal safety conditions. If the virus with an uninspected infectiousness had been generated there, its escape would be no surprise." Journalists want to know.

The Secretary of State wants to know. The Secretary of Health and Human Services want to know. Journalists want to know. Republicans want to know. Americans want know. Why don't Democrats in Congress want to know where this thing started? Is it because Speaker Pelosi called it a diversion last year, when we were raising these questions and asking to have these witnesses brought in front of us?

Or maybe it is because—maybe it is because Dr. Fauci, the all-knowing Dr. Fauci, who Mr. Rogin, in his piece, said has, quote, "repeatedly thrown cold water on the lab leak theory," maybe Dr. Fauci would have to answer some tough questions if we actually dug into how this thing started. Remember, Dr. Fauci gave EcoHealth $3 million. EcoHealth then gave $600,000 to the Wuhan lab. Did Dr. Fauci know about this arrangement when he OKed the grant? Did Dr. Fauci know the Wuhan lab did not operate with the highest level of safety standards, as reported by our own State Department personnel in China.

How about the process? There is a review board at HHS for any grants that do, quote, "gain of function research." Now two weeks ago, Dr. Fauci told Senator Paul that the grant to Wuhan lab was not, quote, "gain of function research," but several respected doctors disagree, say it was. How does this review board process work? Who sits on the board? The truth is, nobody knows. The only thing we know about this board is its chairman, and we only know that because he disclosed it in January 2020. Report here, "Chris Hassell, the chairman, discloses involvement, January 2020, in a talk before the National Science Advisory Board for Biosecurity." He said during the talk that the current definition of what comes

in front of his board is, quote, "very narrow." Quote, "I'll just probably be more frank than may be appropriate. I think it is too narrow." He then went on and suggested that the government could be funding gain-of-function research that his committee hasn't vetted. There are some important questions there for Dr. Fauci.

How about the fundamental question, the fundamental question: Why are we funding research in a lab in Wuhan, China, is the first place? Why are we doing that? I think the American people would like to know, especially what they went through over the last year.

And just as important—just as important, Mr. Chairman, why won't this committee, the only committee in the U.S. Congress focused solely on the coronavirus, why won't we look into how this thing started? I think the American people would like an answer to that question.

I yield back.

Chairman CLYBURN. Thank you for yielding back. The chair now recognizes Mrs. Maloney for five minutes.

Mrs. MALONEY. Thank you, Mr. Chairman, and I thank our witnesses too. I would like to thank them for appearing today, for producing some of the documents that we requested. But I want to note that there are many outstanding documents, even though they were due two weeks ago. And so, I would first like to ask Mr. Kramer, you have received $628 million in a contract. Will you commit to testifying again after we receive these documents and complete our investigation? Will you give us that courtesy? Yes or no.

Mr. KRAMER. Yes, I will, Chairwoman.

Mrs. MALONEY. Thank you. Mr. El-Hibri, will you commit to testifying again after we receive the documents? It is our duty to oversee these documents. It is our charge. We have not received them. Would you commit to testifying, Mr. El-Hibri?

Mr. EL-HIBRI. I do commit, Chairwoman.

Mrs. MALONEY. Thank you very much. We look forward to getting the documents we requested.

I just want to go back to the questions about the inspections. Were you aware in June 2020 of these inspection findings from Johnson & Johnson that there was contamination and there was no plan for the deficiencies that they saw? Were you aware, in June 2020, of these inspection findings, Mr. Kramer?

Mr. KRAMER. I was aware of the report, Chairwoman Maloney——

Mrs. MALONEY. OK. Thank you. And so, you oversee the business operations. In the months after that inspection, what actions did you take to correct them?

Mr. KRAMER. Chairwoman Maloney, our team responded as they do with inspections, whether they be from our clients or from regulatory——

Mrs. MALONEY. I am sure they did—reclaiming my time—but we still had to destroy millions of AstraZeneca's vaccine doses because they were contaminated. And just last week, November 3, you entered into an aggressive stock-trading plan to sell over 10 million of Emergent stock in January and February 2021.

So essentially, right after your company was in the process of destroying, or had destroyed, millions of vaccines that we could have used to save lives, but before this was made public to the people

of this country, you entered into a plan to dump over 10 million of your own company stock, which you knew were going to go down once the problem came to light. So, that makes me think you were more interested in enriching yourself than serving the public. If it was my company, I would be there trying to get it fixed so that we could get the results of the contract.

So far, we have given your company $628 million. They have taken $271 million, and as yet we have not gotten one usable vaccine. Is that correct? We haven't been able to jab one vaccine to save one American life. Is that correct?

Mr. KRAMER. Chairwoman Maloney, there are a number——

Mrs. MALONEY. Yes or no. Yes or no. Have we gotten any vaccines out of your company that we could use?

Mr. KRAMER. Chairman Maloney, those—we have tens of millions of doses——

Mrs. MALONEY. Excuse me. Yes or no. Have we been able to use the vaccine? Have we been able to save someone's life, out of 628 million committed dollars, of which $271 million have been spent, have we been able to get one vaccine? Yes or no.

Mr. KRAMER. None of the vaccines that we have manufactured has been made available to the U.S.

Mrs. MALONEY. OK. We haven't been able to get one vaccine.

But you have been able to sell stock. Were you aware of the problems at the facility when you went out there and sold your stock? At the time you made your stock sale, merchant stock prices were hovering around $120 a share, but the price has now fallen to under $60 a share. Is it true that if you had sold your stocks today instead of before the news of Emergent's contamination, it would have been worth about $5 million rather than $10 million? But I will answer it. You got the $10 million. And instead of thinking of ways to address your company's contamination, you were thinking of ways to enrich yourself. And I am deeply troubled about this. We lost so many lives. If we had the vaccines we would have saved those lives. And I am concerned how you were able to get a no-bid, sole-source contract to prepare a vaccine that you had no experience in doing, and, in fact, the experiences from your past contract, for BioCorp, for anthrax, according to government oversight, was a disaster. GAO said that it was not done well, that they couldn't use it, that it is half of the strategic national stockpile, and scientists are saying it is not needed, and all these questions about the production of bio, and now you get another one. How do you get a contract when your track record was so poor on the first sole-source contract?

Chairman CLYBURN. We are going to hold his answer to that question for the next round, Chairman Maloney.

Mrs. MALONEY. I yield back.

Chairman CLYBURN. The chair now recognizes Dr. Green for five minutes.

Mr. GREEN. Thank you, Mr. Chairman and Ranking Member Scalise, and I want to thank the witnesses for being here today. As a physician who researched vaccines, I helped write a protocol on a vaccine at USAMRIID when I was there, in my Army days, I have followed the development of these vaccines very carefully, especially as we received real-world data from the widespread vac-

cination population. The three vaccines that are being used in the United States are remarkably effective, preventing the infection and transmission of COVID–19. Over 150 million people have received at least one vaccine dose. More 115 million are fully vaccinated, with more being vaccinated every day.

The results are incredibly clear. The CDC issued guidelines. The CDC's guidelines were that if you are vaccinated you don't have to wear a mask inside a building.

Dr. Monahan very quickly had a knee-jerk response to that, using his medical decisionmaking, and said, "Yes, you know what? You don't need to wear a mask inside a committee room." Within 4 days he had reversed his opinion and said, "Wait a minute. Sorry. You can get into an elevator without a mask on, with as many people as you want, and not social distance, but you have to wear a mask inside a committee room." I want to know, what data changed in those four days that his medical decisionmaking changed. Or was there influence from people who just want to continue to exert control.

I will be having a conversation later with Dr. Monahan to figure that out. Obviously, I think that that is an issue, so we will take that up with Dr. Monahan.

I would like to take an issue with at least the implications of some of the comments made by my colleagues across the aisle. Democrats hate bonuses. They hate them. They hate when innovation is rewarded. They want equity of outcomes. That is the big push from progressives. And that is why President Biden is considering giving away these companies' intellectual property on messenger RNA technology. You can't have these American companies making billions of dollars off of the technology that they have been working on for decades.

But oh, by the way, it is OK if we give it to China. Let's let them take it and let their pharmaceutical companies make billions of dollars. Let's let their state enterprises subsidize those companies and put American companies out of business. Great idea. Let's put our pharmacologic biomedical research guys out of business by sharing the very technology that has made them distinct. Great idea. Not a great idea.

Look at Motorola. They went to do business in China. They were forced to share their intellectual property on cell towers with the Chinese government. They gave that technology to Huawei. That company was worth about $11 billion in 1992, and in 2011, I think, 2009, they were scrapped for $900 million because Huawei stole the technology, and with funding from the Chinese government put that American company out of business. Fifty thousand Americans lost their jobs. Do you want that happening in our biotech industry? President Biden, do you want that in our biotech industry? You would share the intellectual property, the efforts of hundreds of American scientists. Just give that away to the Chinese Communist Party.

And oh, by the way, also very concerning, worse than all of that, messenger RNA has a dual-use national security implication. And if biology is a war-fighting domain, and the Chinese have said it is, giving them, handing them this technology on a silver platter is a threat to national security. And yet, here we are, thinking

about sharing the intellectual property of these companies, interestingly enough, who have gotten assistance from the American taxpayer.

This industry is a proud American innovative industry. It needs to be protected. Yes, we need better vaccine distribution globally to help people who are hurting. I am the ranking member of Western Hemisphere on Foreign Affairs, and we need—China is out there giving away its ineffective vaccine, trying to steal relationships, compelling Paraguay to deny its relationships with Taiwan so that they can get the vaccine. China trading the lives of people for, you know, disrespect to Taiwan, their political endeavor. And here we are talking about sharing our intellectual property on messenger RNA technology with China. Ludicrous.

I yield.

Chairman CLYBURN. I thank the gentleman for yielding back. The chair now recognizes Ms. Velázquez for five minutes.

Ms. VELÁZQUEZ. Thank you, Mr. Chairman. Mr. El-Hibri, in 2017, former President Trump nominated Dr. Robert Kadlec to serve as the Assistant Secretary for Preparedness and Response for the Department of Health and Human Services. Mr. El-Hibri, you and Dr. Kadlec had a professional relationship for many years before he was appointed to serve in the Trump administration. Is this correct?

Mr. EL-HIBRI. That is correct.

Ms. VELÁZQUEZ. What kind of relationship was this? Did you work together?

Mr. EL-HIBRI. Yes, we did work together. We worked together in——

Ms. VELÁZQUEZ. OK. No, no, no. This is a yes-or-no answer.

The Select Committee has received documents showing that Emergent paid Dr. Kadlec's consulting firm an annual retainer of $120,000, between 2012 and 2015. Mr. Chairman, I have the exhibits here, 23, 22, and 24, and that shows a total of $360,000. Was Dr. Kadlec paid $120,000 each year?

Mr. EL-HIBRI. I trust that your information is correct.

Ms. VELÁZQUEZ. Was Kadlec paid a total of $360,000?

Mr. EL-HIBRI. Yes.

Ms. VELÁZQUEZ. Did Dr. Kadlec receive payment from Emergent outside of his retainer? If so, how much?

Mr. EL-HIBRI. No, he didn't.

Ms. VELÁZQUEZ. I remind the witness that you are under oath.

Mr. EL-HIBRI. I am not aware that he received any other compensation.

Ms. VELÁZQUEZ. Dr. Kadlec ended his consulting practice in 2015 to go and work for Senator Richard Byrd. But just two years later he became the Assistant Secretary for Preparedness and Response, where he had great influence over large amounts of taxpayer dollars.

In 2017, one of Emergent's business goals was to see that the Strategic National Stockpile, then worth $7 billion, was transferred from the Centers for Disease Control and Prevention to the Office of the Assistant Secretary for Preparedness and Response.

Mr. El-Hibri, when was the Strategic National Stockpile transferred to ASPR control?

Mr. EL-HIBRI. I believe it was in 2018.

Ms. VELÁZQUEZ. OK. This move also played out well for Emergent. In 2019, ASPR awarded Emergent a 10-year, $2 billion contract for smallpox vaccines, and a $261 million order for anthrax vaccines. Then, in 2020, ASPR awarded more than $680 millions to Emergent.

Mr. El-Hibri, how often did you speak to your former business associate, Dr. Kadlec, when he served as Assistant Secretary?

Mr. EL-HIBRI. I would say maybe four or five times during a two- or three-year period.

Ms. VELÁZQUEZ. And how often do you speak to him when Emergent received contracts for vaccines in 2019 and 2020?

Mr. EL-HIBRI. When there is an outstanding RFP.

Ms. VELÁZQUEZ. Did you speak often?

Mr. EL-HIBRI. During an open RFP period, I do not speak with him.

Ms. VELÁZQUEZ. How about you, Mr. Kramer? Did you or any other Emergent executives speak to or socialize with Dr. Kadlec while these contracts were being issued?

Mr. KRAMER. Congresswoman, I did not have any conversations with Dr. Kadlec about this.

Ms. VELÁZQUEZ. It is striking that Emergent profited so much after their former consultant received an influential appointment.

With that I yield back, Mr. Chairman.

Chairman CLYBURN. Thank you, gentlelady, for yielding back. The chair now recognizes, for five minutes, Ms. Malliotakis.

Ms. MALLIOTAKIS. Thank you, Mr. Chairman and ranking member. Everyone, including the President, is talking about bringing our supply chain home, particularly when it comes to the pharmaceuticals. Everyone is talking about manufacturing in the United States. It was something that he made very clear during his state of the Union address as well through Executive order.

But what I don't understand are the policies that have been coming forward that don't achieve that goal. President Biden recently announced that he was green-lighting sending American vaccine intellectual property to foreign countries. This was mentioned by some of my colleagues before. This is something that I don't think any American can understand, and it is a plan to cave to progressives, it is a plan to disseminate American innovation, a plan to keep the U.S. from responding to future pandemics, and a plan, by the way, that has been internationally condemned. A U.S. spokesman for the German Chancellor Merkel said, quote, "The protection of intellectual property is a source of innovation. It must remain so in the future." The German chancellor is looking out more for the American people that our President.

Without properly protecting American intellectual property, there are no future innovations. That is what I hope that my colleagues understand, and it is one of the top reasons why we have lost manufacturing jobs to other countries, particularly the Communist Party of China. And it is the demonization that we are hearing here today of our private partners. It is entering climate agreements that actually give China and India a clear advantage. There is no level playing field. And it is proposals like the President's to increase the corporate tax rate so the highest level in the modern-

ized world, that is a reason why we are having difficulty in finding a manufacturer to even produce this vaccine.

So, I would like to just phrase my questions to talk about intellectual property and how that is going to affect future innovation. Mr. Kramer, are strong IP protections vital to responding to novel emerging diseases?

Mr. KRAMER. Congresswoman Malliotakis, I think it is important that IP protections for manufacturers and for the pharmaceutical companies who own these products, that they are protected. At the same time, I think it is important to focus on what is the ultimate goal. And if the ultimate goal is to make sure that the millions, if not billions of individuals around the globe who need access to vaccine, I think there are different ways to accomplish that goal.

Ms. MALLIOTAKIS. OK. And if you would like to share some of those with me I would appreciate that.

Mr. KRAMER. I would simply say, again, IP protection is important. Pharmaceutical companies like ours and many of our partners, invest millions, if not billions of dollars in constructing and creating that IP, and it is important to respect that.

Ms. MALLIOTAKIS. Thank you. It is my understanding that the Trump administration tried different angles to get this vaccine produced. They had difficulties finding manufacturers within the United States who would be willing to take the risk. Can you talk a little bit about the type of risks that companies like yours, who make drugs that respond to biothreats, take on?

Mr. KRAMER. Yes. Thank you. I think it is important to recognize that the ultimate goal of any manufacturer of a vaccine, whether it is the J&J vaccine, or Pfizer, or Moderna, our collective goal is to ensure that there is a consistent manufacturing supply and reliable process that meets all of our quality standards to make these critically needed vaccines available.

In order to do that, it is very complex. You need a combination of qualified raw materials, a trained work force, dedicated equipment, a properly controlled environment, and all around that you need proper quality controls and checks. That process, to get to that steady state, often requires years and years of work, and we were asked to do that in a matter of months. And I say that not to be a prelude to making any excuses for the work that we have done, but rather that when the FDA concludes that companies like ours have adequately met all those standards, and they put their approval on FDA-released material, that should give the public comfort and confidence that those products are safe and effective.

The other thing I would say is once that state of readiness and repeatability is achieved, the last thing that you want to do is either to change that process or to move that process or, heaven forbid, stop that process, because it does call into question the continuity of that, which is ultimately critically important.

So, we all strive for getting to that state of control and quality operations for our vaccines.

Chairman CLYBURN. The gentlelady's time has expired. The chair now recognizes Mr. Foster for five minutes.

Mr. FOSTER. Thank you, Mr. Chair. I would like to start by just making a couple of quick points. First, that the origins of SARS-CoV–2 will be investigated by the House Science Committee Inves-

tigations and Oversight Committee, and as chair of that committee, I can assure you that our hearings will be a rational discussion among scientists, rather than a blizzard of semi-informed talking points designed for social media.

Second, the idea of manufacturing vaccines in parallel with their test and approval did not originate with Trump's Operation Warp Speed. The Gates Foundation was doing this back in February and March, and telling Congress to do likewise.

Then, in April 2020, in a bipartisan letter led by then Member Donna Shalala and I, signed by 35 bipartisan Members of Congress, we told HHS and FTC, quote, "Congress has given you clear direction and funding to invest in multiple routes to mass production, for multiple, plausible vaccine candidates in advance of their testing and approval, with the acknowledgement that much of that capacity will likely go unused when the final set of vaccines is chosen for mass deployment. We re-emphasized that direction from Congress, and ask you to inform Congress immediately if it appears that mass production capabilities, or significantly promising vaccine candidates are being delayed for economic reasons." So, we gave them money and clear direction in advance of Operation Warp Speed's launch.

But that is not what we are talking about here. I would like to first off re-emphasize that these vaccines are safe and effective and critical to the health, not only of the person being vaccinated but to their families, friends, and the communities they live in. But that only works if the vaccines are properly manufactured.

Mr. Kramer's testimony seemed to imply that the contamination incident was a sort of unavoidable, one-off, random incident that could not have been predicted. But Emergent's Bayview plant has been repeated cited by the FDA, other Federal agencies, and private auditors in recent years for having poor manufacturing practices.

Mr. Kramer, on a recent call with investors you admitted that, quote, "Cross-contamination is a well-known risk when producing drug substance from multiple viral products in a single plant." So, Mr. Kramer, is it fair to say that you were aware of this risk before your company proceeded to ruin millions of coronavirus vaccines through cross-contamination?

Mr. KRAMER. Congressman Foster, it is a well-known risk that if the precautions are not taken there is a likelihood of a cross-contamination. We took that risk seriously, we took all appropriate precautions to prevent that from happening, and, unfortunately, one incident did result in a cross-contamination. We take that very seriously. We have put in place a number of corrective actions since that incident occurred, including strengthening our training, strengthening our cleaning, and removing, quite frankly, the AstraZeneca virus and vaccine from our facility to eliminate that risk from happening again.

Mr. FOSTER. OK. I am also a little bit confused about the statement that you just made under oath, that it was your internal QA checks that first caught the contamination. So, where exactly was the laboratory which first detected the contaminated batch?

Mr. KRAMER. Congressman Foster, I think I recognized that our quality control systems——

Mr. FOSTER. Answer the question. Where was the laboratory that caught the contamination? Was it your internal QA laboratory, you know, process, or was it that of your customer?

Mr. KRAMER. The particular assay and the location of the work that detected the contamination was the J&J facility in Leiden.

Mr. FOSTER. In the Netherlands. So, why did you refer to that as your internal QA checks that detected the contamination?

Mr. KRAMER. Part of our robust quality controls and quality systems include a number of assays that we have done. In this particular case——

Mr. FOSTER. But they did not detect the contamination. Correct? It was detected by your customer seeing a defective batch being delivered.

Mr. KRAMER. That assay that was conducted by J&J was part of our quality control system. So yes, it was detected by J&J, but that test was part of our internal quality control procedures.

Mr. FOSTER. OK. I am highly confused about how you refer to your internal procedures as those of simply your customers making sure that you have delivered a product that conforms to specs.

The record also shows that you should have been on very high alert for those sorts of risks. The Select Subcommittee released new documents today that add to the mounting pile of evidence showing that Emergent had plenty of warnings regarding inadequate conditions at your facilities, yet Emergent failed to act.

And I will have more questions in my next round of questions. I yield back.

Chairman CLYBURN. Thank you. The chair now recognizes Dr. Miller-Meeks for five minutes.

Mrs. MILLER-MEEKS. Thank you, Mr. Chair. Thank you all for coming before the subcommittee today to testify. We have spoken extensively about diversified supply chains and bringing especially the manufacturing of PPE and pharmaceuticals back to the United States. How many facilities, Mr. Kramer, are there in the United States that manufacture vaccines?

Mr. KRAMER. Congresswoman Miller-Meeks, I don't have that number. I don't know.

Mrs. MILLER-MEEKS. OK. Mr. Kramer, when, and under what Presidential administration did Emergent receive its CIADM contract to begin construction on the Baltimore facility?

Mr. KRAMER. It was under the Obama Administration.

Mrs. MILLER-MEEKS. And who was Vice President at that time?

Mr. KRAMER. I believe Joe Biden.

Mrs. MILLER-MEEKS. And did the contract state that you were, quote, "Nimble, flexible capacity to produce medical countermeasures in the face of any attack or threat, known or unknown, including a novel, previously unrecognized, naturally occurring, emerging infectious disease," end quote?

Mr. KRAMER. I believe that is correct, yes.

Mrs. MILLER-MEEKS. And since you are an expert in this area, does coronavirus meet those terms?

Mr. KRAMER. I believe so, yes.

Mrs. MILLER-MEEKS. So BARDA, not the Trump administration, just exercised a task order on that Obama-era contract. Correct?

Mr. KRAMER. That is correct.

Mrs. MILLER-MEEKS. When did the FDA initiate an inspection of your Baltimore facility?

Mr. KRAMER. The last FDA inspection was in April of this year.

Mrs. MILLER-MEEKS. And when did Emergent announce its agreement with the FDA to suspend operations?

Mr. KRAMER. Near the conclusion of that last FDA inspection.

Mrs. MILLER-MEEKS. And are you currently working with the FDA to remediate these issues?

Mr. KRAMER. We are. Immediately following the last FDA inspection, which I believe ended on April 20, we began work on our corrective action plan and our response to the 43 observations. We submitted that comprehensive plan on April 30, and the FDA is currently is under review.

Mrs. MILLER-MEEKS. In fact, the Biden White House said your quality control worked as it should. Did quality control catch these issues?

Mr. KRAMER. Yes, it did.

Mrs. MILLER-MEEKS. Were any Americans harmed?

Mr. KRAMER. No, they were not.

Mrs. MILLER-MEEKS. When you are awarded contracts, do they come from nonpartisan career contracting officials?

Mr. KRAMER. Yes, that is true.

Mrs. MILLER-MEEKS. So, the Democrats' claim of a political gift is just false. In fact, Biden's Director of BARDA said he is 100 percent confident that this contract was awarded based on merit and science and not undue influence.

Recently, Dr. Roger Ebright of Rutgers identified a research article by the Wuhan Institute of Virology scientist, "Discovery of a rich gene pool of bat SARS-related coronavirus provides new insights into the origin of SARS-Coronavirus, and it qualifies as a gain-of-function and was clearly a product of NIH funding." The paper, drafted by WIV scientists clearly states that the underlying research was funded by, among other entities, the NIH. NIH's own data base of grantees list the research and confirms that over $660,000 was spent supporting it.

Perhaps we should focus more on investigating where this virus came from, and if it emanated from a lab which had some funding from NIH and Dr. Fauci, rather than trying to make it more difficult for vaccines to get into the arms of American citizens.

Thank you. I yield back my time.

Chairman CLYBURN. I thank the gentlelady for yielding back. The chair now recognizes Mr. Raskin for five minutes.

Mr. RASKIN. Thank you, Mr. Chairman. Mr. Kramer, here is what I don't get. On six different occasions there were inspections and audits, in the spring and summer of 2020, that ended with warnings to Emergent that you need to take urgent action to improve conditions at the facility, to retrain the staff in order to prevent cross-contamination, and yet still there was cross-contamination, and millions of vaccine shots ended up being destroyed. Is that right?

Mr. KRAMER. Congressman Raskin, we were aware with the number of audits, and we treat all of that audit information seriously. We ways respond with corrective actions to those audits and take all possible precautions from it happening again. As we de-

scribed, unfortunately there was the one contamination, the cross-contamination issue that occurred earlier this year, and we are doing everything we can to remediate and to prevent that from happening again.

Mr. RASKIN. Can you explain in more detail how that happened, if you had been responding to these multiple warnings?

Mr. KRAMER. I am not sure I understand the question.

Mr. RASKIN. How did the cross-contamination take place?

Mr. KRAMER. The cross-contamination occurred as a result of material that was leaving the AstraZeneca suite following a production cycle and production run. And as it was being exited out of our facility it came in the general vicinity of some media that was being prepared for the initiation of a J&J run. So, we don't know exactly the virus of the AstraZeneca product was transferred into the media, but somehow it was. It is our determination, based on that root cause investigation, that that is how the virus was in the J&J product.

Mr. RASKIN. But how did Johnson & Johnson first discover it?

Mr. KRAMER. There are a number of samples, Congressman Raskin, that are taken throughout the manufacturing process as we monitor the production runs, and as I was describing earlier, one of those quality control tests we had asked J&J to perform at their facility in Leiden, since they are experts and are much more experienced at that test than we are, that was where the first sample was detected as being out of specification.

Mr. RASKIN. OK. I want to ask you about the bonuses. Shortly before you had to destroy 15 million of the Johnson & Johnson vaccine shots the company's board found that your executive vice president responsible for manufacturing, Mr. Kirk, had significantly exceeded performance in 2020, that year, right then, and awarded him a bonus of over $360,000 on top of his normal salary, bringing his total compensation, as I read it, to $1,778,627. How did you make the decision to give him a bonus in the middle of this cross-contamination event and this debacle in the production process?

Mr. KRAMER. Congressman, throughout 2020, Mr. Kirk played an integral role in interfacing with our corporate clients as well as with BARDA and HHS Operation Warp Speed. Sean Kirk was working literally around the clock, 24 hours a day, for months on end in order to supervise and direct all of the work that was being done. I think what needs to be underscored is the incredible challenge and the work that was required to get both of these candidates, AZ and J&J, up and running in an incredibly short period of time, under——

Mr. RASKIN. Well——

Mr. KRAMER [continuing]. Extraordinary conditions.

Mr. RASKIN [continuing]. Forgive me. One of our colleagues said that Democrats evidently don't believe in bonuses. I think we definitely believe in bonuses for success, but we don't believe in bonuses for failure. And wouldn't you agree that this was a catastrophic failure in the process, and how can that be rewarded with, I think he ended up with $420,000 in a bonus? I mean, what would it take for someone not to get a bonus?

Mr. KRAMER. So, I don't agree that it was a failure. Our company's work, in this case Mr. Kirk's work, was extraordinary. The amount of work that was accomplished, the progress that was made to advance these two candidates into manufacturing development, and get them in the state of readiness to be prepared to respond to the pandemic was incredible.

Mr. RASKIN. Weren't there two separate episodes of contamination at the Bayview facility, not one, and didn't it result in the destruction of, I think it was 10 million vaccines?

Mr. KRAMER. I think it is important to note that there was a cross-contamination, which I described, with the J&J product. There were a number of contaminations while we were starting up the AstraZeneca manufacturing process, which you would normally find. Again, when you startup a biologic manufacturing process it requires an incredible amount of trained work force, manufacturing steps in order to get the process right.

I think what has not been reported accurately is the fact the package of IP that we received from AstraZeneca, under normal circumstances that would be well defined, you would bring that into your manufacturing facility and be able to quickly replicate that. That was not the case with the AstraZeneca product. And, in fact, we ended up making 80 different process changes alone in the first 60 to 90 days of trying to stand that manufacturing process up. So, it was very difficult, very complicated, and it did result in a number of lost production runs.

Mr. RASKIN. Thank you for that. Thank you, Mr. Chairman.

Chairman CLYBURN. The time has expired. The chair now recognizes Mr. Krishnamoorthi.

Mr. KRISHNAMOORTHI. Thank you, Mr. Chairman. Mr. Kramer, in May 2020, Emergent was contracted to receive $628 million to reserve and prepare its Bayview facility to produce vaccine. Correct?

Mr. KRAMER. That is correct.

Mr. KRISHNAMOORTHI. And under the terms of that contract, Emergent was required to maintain its facility, quote, "in a state of readiness to perform current good manufacturing practices." You don't dispute that, right?

Mr. KRAMER. That is correct.

Mr. KRISHNAMOORTHI. And a month after the contract was awarded, Janssen Pharmaceuticals performed an audit that found, quote/unquote, "mold issues at the Bayview facility."

FDA, in April 2021, found that the building used for manufacturing vaccine, quote, "is not maintained in a clean and sanitary condition." You don't dispute that. Correct?

Mr. KRAMER. I believe that is correct, yes.

Mr. KRISHNAMOORTHI. And FDA found paint peeling on the floors and walls. You don't dispute that either, right?

Mr. KRAMER. I believe that is correct, yes.

Mr. KRISHNAMOORTHI. And you don't deny that the FDA found brown residue and black residue on plant walls. Correct?

Mr. KRAMER. I am not aware of that particular finding.

Mr. KRISHNAMOORTHI. Yes. It is on page 3. I have got to tell you, Mr. Kramer, my son, my teenage son's room gives your facility a run for its money in terms of its cleanliness. And, you know, on

page 8 of this FDA report, which I have right here, it says Emergent, quote, "has failed to adequately train personnel involved in manufacturing operations, quality control sampling, and engineering operations to prevent cross-contamination of both drug substances." You don't deny that that FDA found that, right?

Mr. KRAMER. That is correct.

Mr. KRISHNAMOORTHI. So, it is no surprise that late last year Emergent had to toss out five batches of AstraZeneca vaccine, amounting to roughly 10 to 15 million doses of vaccine, and then yet again, as you testified this morning, you had to throw out, discard, destroy, bulk drug substance amounting to 15 million doses of J&J vaccine.

Now let me point you to the scorecard for what you folks actually achieved. In 2020, you received a contract for about $648 million—that is two or three contracts. You personally were paid $5.6 million in 2020, and the number of usable doses delivered to the American people was a grand total of, you guessed it, zero. Zero. A spectacular failure. And yet, in a February 2021 meeting of the compensation committee of Emergent's board of directors, I will show you what was presented to them. They said you, quote/unquote, "significantly exceeded expectations for 2020." I have got to tell you, Mr. Kramer, if you look at this chart right here, given the fact that no usable doses made it into anyone's arms, you did not significantly exceed the American people's expectations.

Interestingly, that same presentation recommends that you get a bump from $5.6 million in 2020 to $7.8 million in 2021. That is this year. You earned $3.7 million in 2019, so you experienced a 51 percent increase in your compensation, amounting to almost a $2 million increase.

Sir, given that you take full responsibility for what happened in 2020, that you apologized to this committee today, sir, would you commit to turning over your $1.9 million bonus to the taxpayers of America?

Mr. KRAMER. Congressman, I will not make that commitment, no.

Mr. KRISHNAMOORTHI. I didn't think so, sir. In fact, in 2020, you were evaluated for 2020, the compensation committee said you, quote, "ensured successful execution of all six corporate goals." Unfortunately, none of those six corporate goals related, in any way, to the number of vaccines that you put into American arms.

Now you wrote in an op-ed, in the Baltimore Sun, that, quote, "People in our country, or at least some in our media, tend to put a target on the backs of people doing good." You don't think that you are testifying before us because we thought you did good in 2020, do you?

Mr. KRAMER. Uh——

Mr. KRISHNAMOORTHI. I didn't think so. Thank you. I yield back.

Chairman CLYBURN. The gentleman's time has expired.

We now will take a five-minute break before the second round. Thank you. We stand in recess for five minutes.

[Recess.]

Chairman CLYBURN. The committee will come to order. We will now proceed with our second round of questions. I now recognize myself for five minutes.

Last month, the FDA released an inspection report detailing new findings about Emergent's previous failures, and found that many of the company's manufacturing problems were still unresolved. I have a chart here behind me that indicates some findings. The FDA found that even after Emergent was made aware of three separate incidents of vaccine contamination at the Baltimore plant, the company failed to, quote, "conduct thorough investigations."

Now if you look at these findings here, "Emergent failed to conduct thorough investigations," "Emergent's vaccine production facility is not maintained in a clean and sanitary condition," "Emergent's procedures to prevent cross-contamination are not followed," "Emergent failed to adequately train personnel to prevent cross-contamination of bulk drug substances," Mr. Kramer, is there an excuse for this kind of finding?

Mr. KRAMER. Mr. Chair, we take those findings very seriously. It is always disappointing when you have any finding of deficiency. I think what is important is that with our response to the FDA on those observations that we have put together and submitted to them on April 30, included a number of significant and robust remediation plans and corrective actions, including significantly increasing the housekeeping and sanitization process. We made a number of improvements to the personnel and material flow and the design for that activity throughout the facility. We have also undergone a number of training programs for all of the employees in Bayview on viral contamination risk and how to avoid it, good manufacturing procedures.

So, we are taking all those actions seriously, including the replacement of any floor or surface activity throughout the facility in order to be responsive to those observations. We submitted that to the FDA on April 30. We look forward to their feedback, and importantly, we think that those robust corrective actions will put us back on track to resume production soon.

Chairman CLYBURN. Well, may I ask, when do you plan, or what are your expectations about resuming production?

Mr. KRAMER. Sir, as we articulated to the FDA in our response to the 483 plan and observations, there were a number of steps that we suggested be implemented before we would resume production. We have made significant progress against all of those commitments. We are very close to completing them, and I would expect we will be in a position to resume production within a matter of days.

Chairman CLYBURN. Well, Mr. Kramer, you may recall at the beginning of my opening statement I made it very clear that this was the beginning of an investigation, and we have asked for some documentation, which we have not yet received. Now will you commit today to getting those documents to the subcommittee so that our investigation can go forward?

Mr. KRAMER. Absolutely. Yes, sir.

Chairman CLYBURN. Well, thank you very much, and with that I will yield to the ranking member for five minutes.

Mr. SCALISE. Thank you, Mr. Chairman. I want to get back to the question about the 100 million or more doses of the Johnson & Johnson vaccine that are in your facility. I don't know if there has been any determination made, but it sounds like the FDA has

not resolve this issue. Is there any concern that those were contaminated, or are these 100 million doses that more than likely are safe and need to be adjudicated by the FDA? Can you explain, how long has the FDA been sitting on that?

Mr. KRAMER. The FDA is evaluating, to my understanding, the doses that have been manufactured for bulk drug substance that most of which has been provided to J&J. As far as I understand, there have been requests for some additional testing on all of those lots and doses that have been provided by J&J to the FDA, and it is under their evaluation right now.

Mr. SCALISE. How long have they had it?

Mr. KRAMER. I think they have had some of the data for probably a week or two.

Mr. SCALISE. And, Mr. Chairman, I wish the FDA was here, because, you know, if there are 100 million doses, I know one of the successes of Operation Warp Speed was that President Trump had gotten the FDA directly working with the drug companies that were developing the vaccine so that any time that there was red tape, any time that there was a question about something, they could get an answer within a day, not within weeks—it may be almost a month in some of these cases—where the FDA was working overtime to get these questions addressed. I mean, we are talking about 100 million doses of vaccine that could be all completely fine, safe, and effective.

Obviously, that is a determination that the FDA should be working overtime to do, because again, you have got President Biden talking about giving away the intellectual property to China, for free, giving it away. And, by the way, China doesn't have any ability to start turning around and making that vaccine in a safe and effective way. They have got no track record, by the way, of doing that, if we give it away to them. And in the meantime you have got 100 million doses that FDA should be working overtime to get an answer on, because if it turns out that those are safe and effective, why don't we allow those to get out and used instead of giving the entire intellectual property away?

Let me ask you this, because you work with a lot of companies, not just Johnson & Johnson. AstraZeneca has been mentioned too. You have seen this proposal by the Biden administration to give away the intellectual property for the vaccine of COVID–19. What kind of impact would that have on the ability for companies to come up with, or even be willing to invest the billions it takes to find a vaccine, if they know that for the next virus that is out there that President Biden will give that away too? What kind of impact would that have on the willingness of some of these innovators to even get involved in this, versus just saying we are not even going to try to find a vaccine because if we find it, Biden is just going to give it away.

Mr. KRAMER. Yes, Ranking Member Scalise. I think clearly IP protection is critically important to companies like ours, and importantly to the developers of these critically important products. I have not seen the exact proposal by the current administration so I cannot comment on that, but fundamentally I think IP protection is very important.

Mr. SCALISE. Well, let me ask, Mr. Chairman, if I can ask unanimous consent to get this article included in the record, which talks about the President's plan to give away the intellectual property to China, as well as other countries.

Chairman CLYBURN. Without objection.

Mr. SCALISE. Thank you. There are other countries, by the way, that are watching this. I will give you an example. A spokesman for German Chancellor Merkel just said, quote, regarding the giving away proposal by Biden, to give away the IP, quote, "The protection of intellectual property is a source of innovation and must remain so in the future," close quote. In fact, Germany is criticizing President Biden's proposal to give away the IP because they know what that means and what devastating effect it would have on the ability to get future vaccines.

My God, I mean, isn't it a sad state of affairs that the German chancellor is more concerned about American intellectual property than the President of the United States? I would urge President Biden to talk to some of our other allies around the world who realize this is a crazy idea, to give away our IP to China, who has no track record of even having the ability to make anything safely and effective like a vaccine. It might take them years, and in the meantime we have given away, as Dr. Green pointed out, not only the vaccine but the template for other things that could be used against us by China. This is a dangerous idea we should not do.

Mr. Chairman, I yield back the balance of my time.

Chairman CLYBURN. Thank you, Mr. Scalise. The chair now recognizes Ms. Waters for five minutes.

Ms. WATERS. Thank you very much, Mr. Chairman. As we have reviewed information about Emergent today, of course we find that there was a no-bid contract and that this contract was participated in, in some way, by a former consultant to the tune of $360,000 paid to Robert Kadlec. We also have found that based on testimony today we have learned that Emergent sold stock in what could be considered, or appears to be, insider trading. They have been paid millions of dollars despite destroying millions of vaccine doses.

And they can't be trusted. They have had serious manufacturing problems, multiple inspections and audits that were conducted in 2020, that warned of serious quality control. Evidence recently obtained by the committee shows that Emergent was aware of serious control issues at its Bayview facility, but failed to act. In June 2020, an advisor to Operation Warp Speed identified risks in relying on Emergent to handle the production of two coronavirus vaccines. During a separate audit, Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson, found that the Bayview facility had a deficient contamination control strategy.

On June 17, 2020, Carlo de Notaristefani, the lead manufacturing advisor for Operation Warp Speed, issued a private report on Emergent. The report identified multiple risks at the Bayview facility, including concerns about facility readiness, personnel, and compliance. The report stated most of the large-scale, existing equipment is not suitable for the new processes and will be either removed or mothballed. The supporting infrastructure is very limited and will need substantial remediation and expansion to allow manufacturing to proceed at the planned rate. Personnel risks are

significant. The stacking plans presented seem inadequate to the level of current activities required for all full-scale production of the program.

Let me just say this. The Republicans here today have tried to basically make this an argument about intellectual property. Today this is really not about intellectual property and whether or not we are giving away, or the President is giving away intellectual property. This is about the safety of all Americans and other countries that hopefully we can be involved with in helping them to get the vaccines that they need in order to deal with the problems that have occurred, the pandemic, and all of the other countries who are looking to us for some assistance. And I am hopeful we will be able to do that. But we cannot do that if we are investing in a company like Emergent, who is endangering us all.

And so I would certainly ask this committee not only to continue the investigation but please, based on all of the information that we have, it can be concluded that Emergent should not be in the business of developing vaccines, whether it is trying to work with Johnson & Johnson or AstraZeneca or anybody else, because they cannot be trusted.

And so I am hopeful that the moneys that we are paying, the moneys that the Federal Government is paying for reservation, without getting any result, be directed to another and other companies that have proven that they can safely produce and manufacture the vaccines that are needed to deal with this pandemic.

I thank you so very much for holding this hearing today, Mr. Clyburn. This is so important. But I think we know enough about Emergent not to trust them. Why would we continue to deal with a company that has violated the contract in so many ways, who have a dirty facility, and have us believe that, oh, there may be a contamination because of the way that a vaccines was traveling. No. This vaccine may be contaminated because the facility is dirty. It is not clean. It is not in shape to do the kind of production that they have said they would do, and they are in violation of this contract. As a matter of fact, they should be trying to present themselves from being sued, or jailed because of what they have done.

And this is very serious, and this cannot be swept under the rug. This cannot be, oh, we need it so badly, we have just got to continue with them, despite everything that we know about them, and we need to trust them one more time.

Mr. Chairman, thank you so very much. We should not trust them, not another minute, not another day.

I yield back the balance of my time.

Chairman CLYBURN. I thank the gentlelady for yielding back. The chair now recognizes Mr. Jordan for five minutes.

Mr. JORDAN. Thank you, Mr. Chairman. Mr. Kramer, the government came to you, right? The Obama-Biden government came to you and said, "In the event there is a pandemic, we need to be ready. You are one of the places we think can be ready." So, they initially came to you. Is that accurate?

Mr. KRAMER. Yes, that is accurate.

Mr. JORDAN. And they came to you because you were one of a handful of companies who could do this kind of work. I think you

said in your opening testimony there like two or three of you in the whole country. Is that right?

Mr. KRAMER. That is correct, Congressman Jordan, and, importantly, we have been doing work in the public health threat area for now decades.

Mr. JORDAN. Yes. Mr. Kramer, the government wasn't just like—they just didn't pick you out of a hat and say, "Oh, you are one of the three companies, and there are only three." They came to you because you have got a proven track record. It is my understanding, and Mr. Green served our country in the military, he said he has got all kinds of vaccines that you helped manufacture in his arms. You helped with the anthrax vaccine, the smallpox vaccine. I think you have worked on the Zika virus. You have worked on the Narcan treatment that so many communities around our country have had to have with this opioid crisis. So, you have worked on all those issues. Is that accurate?

Mr. KRAMER. Yes, it is accurate. Thank you.

Mr. JORDAN. And when government came to you this time, they asked you to do something unique. They asked you to ramp up, stand up this facility in a record amount of time, because we were dealing with the COVID virus that, unfortunately the Democrats on this committee don't want to figure out where it started, but we were dealing with a virus we had never really seen, a magnitude we had never really seen before. So, they asked you to do it in a record amount of time, and they asked you to deal with two vaccines at the same time. Is that accurate?

Mr. KRAMER. Yes, it is.

Mr. JORDAN. All the other work, you had only dealt with one at a time in your facility, one vaccine or one issue you were working on, not Johnson & Johnson and AstraZeneca, not Astra Vinegar, as the chairwoman from the Financial Services Committee, but Johnson & Johnson and AstraZeneca. Is that right?

Mr. KRAMER. That is correct, Congressman Jordan.

Mr. JORDAN. And then you had a cross-contamination that you guys found, because of the fact that you had two vaccines you were working on at the same time.

Mr. KRAMER. That is correct.

Mr. JORDAN. And since that was discovered, as the ranking member was just pointing out, you have not been able to use the over 100 million doses of the J&J vaccine that you currently have at your facility. Is that accurate?

Mr. KRAMER. It is, Congressman. Those doses are actively under review by the FDA as we meet today.

Mr. JORDAN. Has your company or J&J raised any concerns—is there anything that tells you those vaccines aren't good vaccines?

Mr. KRAMER. Those vaccines have passed all of our internal quality control measures, and I believe J&J would say the same on their part.

Mr. JORDAN. So, J&J hasn't raised any concerns, you think they are fine vaccines, but they are not being used.

Mr. KRAMER. That is correct.

Mr. JORDAN. And instead, the Biden administration is thinking about giving over the intellectual property to foreign countries, and as we know, we have got some heads of state around the world who

are saying that is a crazy idea. But they are thinking about doing that instead of using the 120 million doses that everyone believes are just fine. That is the situation right now. Is that right?

Mr. KRAMER. I think that is an accurate description, yes.

Mr. JORDAN. So, giving IP to China, the very country where the virus started, that is what the Biden administration is looking at doing, instead of using 120 million doses that Johnson & Johnson and both you all think are just fine.

Finally, I just have a few seconds left. The previous member basically accused you of committing a crime, saying you engaged in insider trading. It is my understanding, from public reports, that the stock purchase that you exercised were determined long before there were any concerns about anything at your facility, and those were on schedule to happen, regardless of any decisions that may or may not have been made. Is that accurate?

Mr. KRAMER. It is accurate, Congressman Jordan, and thanks for the opportunity to clarify. All of my stock sales were made pursuant to the plan that was approved by the company, and importantly, was put in place during a quiet period that was also approved by the company. And most importantly, once that plan was filed, and it was a 10b5–1 plan, my participation was completely removed from the execution of those trades.

Mr. JORDAN. Mr. Chairman, I would just—thank you, Mr. Kramer—Mr. Chairman, I would just add, why won't this committee have a hearing on this IP issue, which is of paramount importance, and just as importantly, why won't this committee, the only select committee in the U.S. Congress, have a hearing on the origins of the very virus that caused all this chaos over the last year, not only in America but around the world?

Chairman CLYBURN. Thank you very much for the questions. I think Mr. Foster answered that question earlier.

Mr. JORDAN. No, he didn't. He said Science is going to look into it at some point. Our charter is very clear, Mr. Chairman. Our charter says "prepare for future pandemics." The best way to prepare for future pandemics is to figure out how this pandemic started, and the fact that the select committee on the COVID virus won't look at how it started makes absolutely no sense to me. But more importantly, it makes absolutely no sense to the American people. Journalists want to know. The Secretary of Health and Human Services wants to know. The Secretary of State wants to know how this started. The only ones who don't want to know are Democrats on the select committee and Democrats in the Congress.

Chairman CLYBURN. Thank you very much. You wanted to know where we have been, I would like to spend some time on where we are going. And with that I will yield five minutes to Mrs. Maloney.

Mrs. MALONEY. Thank you, Mr. Chairman. Thank you, Mr. Ranking Member.

Mr. El-Hibri, if I could ask you a few questions. You testified in 1999, before the Committee on Government Reform, about your company's failure to fulfill its commitments under a contract to produce anthrax vaccine for the U.S. Government. Do you recall that hearing?

Mr. EL-HIBRI. Yes, I do, Congresswoman.

Mrs. MALONEY. And you testified that your company, Bioport, which, as I understand, now is a subsidiary of Emergent, was not meeting commitments because of unforeseen delays. Also that year, the Government Accountability Office came out with a report that said that your company's inability to achieve its business plan, they also said the company could not perform. And it appears that we are having a similar situation today. There is a pattern here. Now, Emergent, your primary company of which Bio is a subsidiary, has been unable to fulfill its commitment to the government. We haven't gotten the vaccines that we ordered.

But not only does your company have a history of underperforming, it has a history of unreasonable price increases. The price you charged the government for a dose of anthrax vaccine increased from $3.35 in 1998, to around $30 in 2020. That is an 800 percent increase.

So my question is, the cost of producing the anthrax vaccine has not increased by 800 percent—I guess the question I want to ask is how much does it cost you to produce a dose of anthrax vaccine? Has it jumped 800 percent? How much does it cost, either Mr. Kramer or Mr. El-Hibri? Do you have that answer, or can you get it to us later?

Mr. EL-HIBRI. We will get you that information later, Congresswoman.

Mrs. MALONEY. I couldn't hear you. What?

Mr. EL-HIBRI. I said I will give you that information later, if I may.

Mrs. MALONEY. OK. Great. And what is Emergent's approximately profit margin on each dose of anthrax vaccine sold in the U.S., and this one, if you could get that to me later, and I will give you some other questions. But what percentage of your sales of anthrax vaccine are to the U.S. Government? Do you export your vaccine to any other country, or do you just sell to America? Do you know, Mr. El-Hibri? Do you sell to other countries or only to America?

Mr. EL-HIBRI. Yes, we do have international sales of anthrax.

Mrs. MALONEY. Could you get us that report on where you sell it over there?

Mr. EL-HIBRI. I will.

Mrs. MALONEY. So, what I find sort of disturbing is really a procurement question. Why does the country give a contract to a company that has a history of not completing the contract, and then on top of it, charging huge price increases, 800 percent? And I think that is something that the committee needs to look at, because this is unfair to the American taxpayer, to say the very least. When you have a contract, you should produce the product. So far, we haven't even gotten one dose of the product out to the American taxpayer, yet you have been able to get bonuses, millions of dollars in pay going out to executives, and they have not completed the contract.

So, I am really posing to my colleagues, we should at least write procurement laws that if you are not producing the product you shouldn't be paid. You certainly shouldn't get a bonus, and you should not give a contract to a company that does not have a track record of completing the task. I, for one, support American manu-

facturing. I come from New York. We couldn't even get gowns or masks. They were walking around in trash bags, going to work in them, because we couldn't produce them. The only time we got them is when we, ourselves, seamstresses, businesses converted overnight to make the personal protection equipment for our people and the vaccines. We did produce vaccines in record time.

So, I feel very strongly that we should have strong procurement laws that gest a good product for the American people. We need to produce our personal protection equipment, our vaccines, and everything else related to a pandemic here in the United States. We cannot rely on other countries, and I believe that is something we need to look at.

I, for one, Mr. Chairman, would like to question whoever approved this contract in the U.S. Government. What were they thinking when they said you could allow a company to increase the cost 800 percent, and that there was no requirement that you actually produce the product before you get paid substantially with bonuses and everything else?

My time has expired. I thank you, Mr. Chairman, for your hard work and all of my colleagues. Thank you. I yield back.

Chairman CLYBURN. Thank you, Mrs. Maloney. The chair recognizes Dr. Green, for five minutes.

Mr. GREEN. Thank you, Mr. Chairman, and I would like to begin my second round of comments just reiterating this issue about the origins of the vaccine. There are multiple articles coming out now that make all sorts of implications. We need to get to the bottom of it. It is a shame this committee has not addressed it. We are the Coronavirus Select Committee, and we haven't even looked at the origins of this thing. We haven't looked at the World Health Organization and their complicitness with China on messaging. Those things have to be looked at.

I was excited to hear that Representative Foster, a gentleman whom I have deep respect for, said that someday that will happen in Science and Tech. I certainly want to ask Representative Foster, what are you all waiting on? Let's get going.

BARDA tasked you guys, talking to our witnesses now, to take both vaccines onto your assembly line, J&J and AstraZeneca. I think, as I understood from your previous testimony, you did think that there was some concern about having both vaccines. Is that correct, that there was potential for problem with you have both on two assembly lines? Is that correct?

Mr. KRAMER. I think it was widely acknowledged by Emergent as well as our network of partners that there was inherent risk of bringing both vaccines into our facility and ramping them up very quickly.

Mr. GREEN. So, that is what I understood to be a risk. And J&J, as I understand it, you guys had 16 batches, one of which was cross-contaminated, 15 of which were not, or at least are still being inspected, and that equals 140 million doses that are waiting to make sure that the FDA is checking to make sure they are OK, and when that happens they get shipped. Is that correct?

Mr. KRAMER. Generally, correct. Yes, sir.

Mr. GREEN. OK. So, these slides that are being shown around where money was given and zero vaccine, granted there are 140

million doses sitting there waiting on FDA approval, that may eventually, maybe next week, be sent to people who need it. OK. Thank you for that.

You know, I am a former military officer. I think most people know that. I deployed all around the world in combat. I took the anthrax vaccine—I think you guys created that—and I really appreciate your work in the biodefense world. You know, even Barack Obama recognized you are one of the only companies that can do this kind of stuff, and gave you business way back when.

Botulism toxin, smallpox—I got the smallpox. You know, after Sverdlovsk we knew that the Russians were weaponizing smallpox, so as we went into Iraq I got another smallpox vaccine, and I really appreciate you guys doing that. Typhoid, cholera. You also do a lot of treatment drugs. I think as an ER physicians, I have used nasal Narcan to save a patient's life, and I think you guys make that too, right?

Mr. KRAMER. Yes, sir, we do.

Mr. GREEN. So, the overdose come into the emergency department, we spray this nasal Narcan, we save their life. That is your company, as I understand it. Correct?

Mr. KRAMER. Yes, sir. That is right.

Mr. GREEN. But you have all these products out there. You had company goals. You were managed by a board. The board set goals for the CEO. Those goals were met—at least that is what the, you know, minutes from the meetings have been read earlier—and bonuses were paid. And as I understand it, everybody in the company got a bonus. Is that right? I mean, can you elaborate on that for just a second?

Mr. KRAMER. Yes, sir. All of our employees are eligible for a bonus based on their individual performance as well as the corporate performance, and separate from that, in 2020, we offered a special equity award of roughly $7,500 in our stock to all of our employees in recognition of the significant——

Mr. GREEN. All these other things. All these many other things that your company is producing and saving lives all across America. So, you gave your folks a bonus for their incredible work in all of these other products. You had one contamination line, 15 other batches, 140 million doses that are sitting there that may get approved and may get sent into arms, and we are here, spending this committee's time, talking about this when we ought to be talking about where this virus came from in the first place.

I cannot believe we are even having this conversation. You are a reputable company that has done yeoman's work to protect this Nation in biodefense. You have one contamination, and they want to take you to court. Yet China, cooperating with the World Health Organization, everybody knows what happened. There is not a human on this planet that doesn't say, "Hey, China screwed all of us," and we suffered more because of it. Yet we can't get this committee to say a word about it. But let's take on this great company who did its best to try to get a vaccine out there. Meanwhile, it is doing all these other things to save Americans' lives.

I yield.

Chairman CLYBURN. I thank the gentleman for yielding back. The chair now recognizes Ms. Velázquez for five minutes.

Ms. VELÁZQUEZ. Thank you, Mr. Chairman. Mr. Kramer, Emergent last year was warned multiple times regarding persistent staffing problems at its Bayview plant in Baltimore. Specifically, in April 2020, the FDA warned in an inspection report, that, and I quote, "Employees are not given training in the particular operations they perform as part of their function." Exactly a year to date later, FDA cited Emergent for exactly the same thing. Is this correct, Mr. Kramer?

Mr. KRAMER. Those observations by the FDA are correct, Congresswoman. We take them very seriously. We have put in place a number of corrective actions to increase our training——

Ms. VELÁZQUEZ. OK. Mr. Kramer, so you are stating that is correct, that the report was correct.

Today, the select subcommittee released an audit report drafted by the lead manufacturing advisor for the former Operation Warp Speed, who found that Emergent had, and I quote, "significant personnel risks." He wrote, and I quote, "The staffing plans presented seem inadequate," and also noted the need for extensive training. Is that correct? Yes or no.

Mr. KRAMER. I haven't seen that report, but I believe that is correct and accurate. I think what is important to recognize is last year at this time, as we started up the process of working with both AstraZeneca and J&J, we incurred a significant staffing challenge, increasing from 100 employees to 400 employees last year. That is always a challenge.

Ms. VELÁZQUEZ. Well, Mr. Kramer, I would like to know, and the members of the select subcommittee would like to know that under your watch, what assessments were in place to guarantee that staffing plans were adequate for the unprecedented crisis at hand?

Mr. KRAMER. I am not sure I understand the question, Congresswoman.

Ms. VELÁZQUEZ. Well, look. Report after report, audit after audit, they found inadequate training. We just want to know that you are taking the necessary steps so that whenever we face again another unprecedented crisis, that you will have what it requires in terms of your personnel and the work force to perform the job at hand.

Another audit performed by BARDA found that Emergent has just one employee coordinating testing to ensure that the materials used for the coronavirus vaccines remain stable. BARDA concluded that the employee's heavy workload likely caused a mistake to be made. Is that true, Mr. Kramer?

Mr. KRAMER. I am not aware of that particular finding.

Ms. VELÁZQUEZ. So, I think we all see a pattern here. And according to The New York Times, as Emergent scrambled to meet the heavy demands of vaccine production, one senior manufacturing supervisor responded to reports of quality errors by asking, and I quote, "Do you want me to make drugs or fix issues? I don't have time to do both."

This is a very concerning pattern with predictable results. I want to make it clear, I am certain that the workers at the Bayview plant have been working very hard, under difficult circumstances, to do their job and manufacture these critically needed vaccines. This isn't about what they are doing. It is about what you haven't done, sir. Why did it take an FDA-imposed shutdown of your plant

for Emergent to find the time to properly train its employees? Shouldn't these employees have been trained before they mishandled coronavirus vaccines?

Mr. Kramer, Emergent needs to do better. You need to do better. You should treat your work force, your employees, with respect, and provide the tools they need in order to perform their jobs.

I yield back.

Chairman CLYBURN. I thank the gentlelady for yielding back. The chair now recognizes Mr. Foster for five minutes.

Mr. FOSTER. Thank you, Mr. Chairman. Mr. Kramer, you have repeatedly emphasized how much you care about employee training and quality control. Does your company spend more on quality control training for employees or on government relations and lobbying?

Mr. KRAMER. I don't have those exact numbers. I do know, Congressman, that we have a significant number of our employees that are dedicated to both quality assurance and quality control, and as I commented earlier, we are using this 30-day period from when the inspection concluded, roughly 30 days ago, to even today, to conduct extensive training for all of our employees in the Bayview site so we can get them prepared to resume production soon.

Mr. FOSTER. Yes. Well, you can generally tell how much an organization really cares about things by looking at how much they spend in different areas. And so if you could get us those numbers for the amount you spend on government relations and lobbying, as well as quality control training, both currently, after you presumably upgraded your game in that, as well as historically, after the last year. I think that would be very informative.

Let's see. Something that is actually more quantifiable or specific. In June 2020, not the government but your customer vaccine manufacturer, J&J, through its subsidiary, Janssen, performed its own audit of Emergent's facilities, and it found that there were, quote, "mold issues associated with the facility shutdown/startup." And then 10 months later, when the FDA came in for an inspection, they found that the building used for manufacture of vaccine, quote, "is not maintained in a clean and sanitary condition," unquote, and that there was, quote, "brown residue was observed on the wall."

So, Mr. Kramer, do you have a knowledge of what this brown residue was?

Mr. KRAMER. I am not aware of the brown residue material.

Mr. FOSTER. So, you generally don't read the FDA inspection reports. Is that correct?

Mr. KRAMER. I do read the majority of the FDA inspection reports. I just don't recall this particular reference.

Mr. FOSTER. OK. So, brown residue on the wall is not something that caught your attention. OK.

And so now I guess one of the things our committee is going to have to be doing is trying to understand the balance of effort going forward in putting our country in a better posture on this. So, do you—actually, either of you—have any advice, if you were in our shoes, as to how to make sure that when we have standby capacity that we have been spending huge amounts of money for, how we should properly exercise that, to know that when the emergency

hits that capability is actually, you know, can be stood up and all of the, you know, nuts and bolts, like quality assurance, is in place so that we have a well-exercised muscle when we need that energizing in the future. Yes, any lesson learned that you think you would pass to us?

Mr. EL-HIBRI. May I answer that, Congressman?

Mr. FOSTER. Yes, please.

Mr. EL-HIBRI. I think the Obama-Biden administration was on the right track to identify manufacturing facilities that are suitable to respond to a future pandemic crisis and emergency. So, I think that concept is a very good concept.

Now what happened over an eight-year period, nine-year period, is that the task orders, in order to keep the facility up and running, weren't adequate over this period of time, so that really the facility, even though it was meant to be at a state of readiness, was not quite at that level. So, we had maybe 100, and sometimes less than 100 employees in any given year, except for those few times where we did get a task order for the H1N1 flu vaccine and for Ebola and Zika.

Mr. FOSTER. So, if you could come up with an estimate of what the total missing investment was during that period, and also the total amount of, you know, high employee bonuses that were issued, just to understand sort of the balance of funding during that period.

Mr. EL-HIBRI. Yes. I will be happy to do that and provide that for you.

I just want to make one thing clear, if I may, which is that when all these audits were performed by AZ and by Johnson & Johnson and by BARDA, this was before they entered into a contract with us, not after. So, everyone went into this with their eyes wide open, that this is a facility that had never licensed a produce, had manufactured a licensed product before, that is a facility that although not in perfect condition, far from it, was the facility that had the highest level of state of readiness. And it was in partnership with Johnson & Johnson and AstraZeneca and BARDA, after they have done their audits, that we agreed to work together to manufacture vaccine at risk. As you have said, that they sent the congressional letter to HHS or to BARDA, saying, "Hey, listen. We need to take risks in an environment where we need to respond rapidly," and this is exactly what the government did. So, I am happy to——

Mr. FOSTER. Yes, the idea of taking technical risk, I think we are all completely on board with. But the idea of just failure to properly execute on the plan, the admittedly risky plan to try manufacturing in several sites, I think that is a different level of question and investigation that we are going to be pursuing here.

Anyway, my time has expired, and I yield back.

Chairman CLYBURN. Thank you for yield back. The chair now recognizes Dr. Miller-Meeks for five minutes.

Mrs. MILLER-MEEKS. Thank you, Mr. Chair. I find it interesting that President Biden stopped construction on the border wall on January 20, but those contracts are still being honored and still being paid. And I would certainly encourage my colleagues who are concerned about taxpayer money being spent when a contract has

not been fulfilled to have support for construction completion of the border wall that has already been paid.

Earlier this month, President Biden endorsed using intellectual property waiver at the World Trade Organization for COVID vaccines and therapies. Not only would a waiver of this kind destroy billions of dollars in U.S. intellectual property by handing over U.S. IP to countries such as Russia and China, but would also set a precedent for future pandemics and pharmaceutical investment. As a former director of the Iowa Department of Public Health, I know first-hand how important it is to have private sector partners working with us to prepare for future emergencies.

Mr. Kramer, how many vaccines do you have sitting your facilities which were not contaminated and could be shared with other countries or put into the arms of Americans?

Mr. KRAMER. I don't have an exact number, and the reason is that we, again, make the bulk drug substance and then we typically ship that to our customers, either J&J or AstraZeneca, and from there they are ultimately responsible for doing the filling, finishing, packaging, and labeling. So, we lose transparency of the equivalent number of doses after we ship our product to them.

Mrs. MILLER-MEEKS. If you were cleared by the FDA today, how quickly could you begin manufacturing more J&J vaccines?

Mr. KRAMER. We would be ready to resume production in the next couple of days.

Mrs. MILLER-MEEKS. And how long does it typically take, in a first-world country such as the U.S., to increase manufacturing capacity and have the infrastructure in place to manufacture vaccines, such as the J&J vaccine?

Mr. KRAMER. It normally would be measured in years, Congresswoman.

Mrs. MILLER-MEEKS. So, is it reasonable to assume that it would take longer in other countries?

Mr. KRAMER. It likely would, yes.

Mrs. MILLER-MEEKS. Well, I think it is interesting that in 2007, melamine pet food from China caused dogs to die and had to be removed. In 2008, in July 2008, milk and baby formula was deliberately adulterated with melamine in order to pass quality control measures. Babies were harmed. In October, similar adulteration to eggs; in 2012, sweet potato dog treats from China causing kidney failure; and in June 2020, manufacturers in China charged with three counts of violating FDCA for misbranded, substandard respirator masks, falsely purported to be N95 standard. The FBI said this was a blatant disregard for the safety of American citizens.

And on March 7 of this year, 2021, The Wall Street Journal, "U.S. officials at the State Department indicated Russian intelligence agencies have mounted disinformation campaigns to undermine confidence in the Pfizer and other vaccines."

With both Russia and China seeking to increase the utilization of their vaccines abroad, overt efforts to denigrate Pfizer have been well documented. So, given these deliberate manufacturing safety violations, not an error, that did not harm anybody, given these deliberate safety violations when we are not in a pandemic and don't have to ramp up production immediately, can you foresee a medical

manufacturing or a national interest in waiving intellectual protection of property for vaccine manufacturers?

Mr. KRAMER. I am not sure I understand completely your question.

Mrs. MILLER-MEEKS. Do you think it is beneficial to the U.S. to waive intellectual property protections for the vaccines to foreign countries, given their manufacturing and safety violations?

Mr. KRAMER. I think there are clearly some risks, as you have articulated.

Mrs. MILLER-MEEKS. And are there other biodefense capabilities here in the United States, to whom would we turn that over to if it were not companies such as Emergent, who are willing to take that risk?

Mr. KRAMER. I think it has been fairly well documented that Emergent is unique in that we have, over the last two decades, focused on public health threats. We manufacture products that, in many cases, are the only products of their nature in the world that are approved by the appropriate regulatory authorities. So, I think that it would be a significant risk.

Mrs. MILLER-MEEKS. Well, as a 24-year military veteran, former director of the Iowa Department of Public Health, and one who has administered vaccines in the 24 counties in their congressional district, I thank you for all the work you have done in biodefense capabilities and helping prepare the United States for this pandemic and future pandemics.

I yield back my time.

Chairman CLYBURN. I thank the gentlelady for yield back. The chair now recognizes Mr. Raskin for five minutes.

Mr. RASKIN. Thank you, Mr. Chair. Mr. Kramer, the subcommittee is releasing documents today which show that Emergent has been charging the U.S. Government $27 million a month to reserve its facilities for use. Can you explain where that provision in the contract came from? You get $27 million a month, as I understand it, regardless of whether or not you produce any vaccine. Is that right?

Mr. KRAMER. The nature of the contract with BARDA that we signed this time last year was to ensure that the U.S. Government, in this case through its agency, BARDA, had immediate access to certain areas within a couple of our facilities. They subsequently, in the case of the AstraZeneca vaccine, directed us to make certain space available in our facility to support the work that we are doing with AstraZeneca.

Mr. RASKIN. OK. And so, did you have any other responsibilities for that $27 million a month, other than just to have the space available if they needed it?

Mr. KRAMER. It was primarily an access matter, Congressman Raskin. I would say that right before this task order was put in place we had been in negotiations with another company to do COVID–19 vaccine work in the facility. So, it was not as if that space was going to go unutilized. We, quite frankly, had another opportunity to do work in that same space.

Mr. RASKIN. OK. But there was nothing in the contract then, as you read it, that required you to bring the facility up to par, so that it met standards in the event that it was needed to be used. In

other words, you had no obligation to do anything that would have prevented the problems that you later encountered.

Mr. KRAMER. The nature of the task order was to make sure that the government had access to certain areas of our facility so they could direct additional vaccine development and manufacturing work, at their priority, to Emergent.

Mr. RASKIN. OK. And I know that you touted this arrangement as one of the primary drivers of your big profits in 2020, on one of your earnings calls, so you were obviously aware, this was good deal. Where did that $27 million figure come from? Have you ever been able to charge that before to a private customer?

Mr. KRAMER. The dollar figure is really based on different activity on a per-production-run basis that is market rate. We were in lengthy negotiations with another party to utilize that same space at essentially that same rate of production suite time.

Mr. RASKIN. I see. So, they were paying you basically $27 million because somebody else was about to pay you $27 million, as a monthly fee for the use of the facilities. Is that right?

Mr. KRAMER. Yes, I think the interest by BARDA and the U.S. Government was to ensure that they had availability to much-needed capacity to make COVID–19 vaccines.

Mr. RASKIN. OK. I understand that HHS is deducting some of that money, not paying for all of it for the failures in actually being able to produce the vaccine. And so, first of all, did you accept that, that HHS is withholding some of that money, and what kind of restitution do you think is owed the taxpayers for the failure to produce any vaccine once that part of the contract was activated?

Mr. KRAMER. So, I am not aware that there is any reduction in the contract value that is being exercised by the government, so I am not aware of that.

Mr. RASKIN. OK. So, you are expecting $628 million for essentially the reservation of this space, regardless of whether or not you are able to deliver on the vaccine.

Mr. KRAMER. The task order that was put in place this time last year, in total, was approximately $628 million. It included a portion for what you are referring to, which was the reservation fee. There was also roughly $85 million of funding for some additional fill finish equipment, and the installation of that, in order to increase drug product or fill finish capability at another one of our sites here in Maryland.

Mr. RASKIN. OK. I got you. Well, Mr. Kramer, thank you for your testimony. Mr. Chairman, I just wanted to say, you know, with more than a half a billion dollars involved in this project, I hope we can get to the bottom of whether this contract and its terms were really, in fact, fair terms, and whether that is what the taxpayers have a right to expect.

And I turn it back over to you, Mr. Chairman.

Chairman CLYBURN. I thank the gentleman for yielding back. The chair now recognizes the ranking member for any closing statement he would like to make.

Mr. SCALISE. Thank you, Mr. Chairman. I appreciate the hearing today, and Mr. Kramer, I appreciate the testimony you gave.

One of the things that we should be pushing for that comes out of this hearing, Mr. Chairman, is that as the testimony revealed

there may be over 100 million doses of the Johnson & Johnson vaccine that could be OKed that are being held right now, help up, that could be in the arms of people. The FDA, as we saw with Operation Warp Speed, where the red tape was cut, where we pushed Federal agencies to work smarter and faster, turn things around quicker, all hands should be on deck to get that answer. And if, as both Emergent and potentially Johnson & Johnson's internal reviews have said, that those 100-plus million doses are OK, then why hold them up?

I mean, you have got the Biden administration right now talking about giving away the intellectual property of this vaccine to China, for free, undermining the very protections that our American companies enjoy, that encourages them to go out and create new vaccines. If you give that away you will send a chilling effect on any company going out there on a limb and saying, "We are going to put up our money to find a vaccine for the next thing," whether it is ALS or Alzheimer's or cancer, or a future virus that might be started by China. That would be gone. And instead you have got 100 million doses that could be going to put into use, saving more lives. FDA needs to get us that answer. They need to get that issue resolved quickly.

But it gets to the bigger question. Mr. Chairman, President Biden needs to just come out and say he is not going to give away our IP. Our friends around the world are saying this would be ridiculous to do. When the German Chancellor is saying, "Don't do it," because they know how dangerous that would be, especially giving it to China, who does not have a good record, not only on intellectual property—it is bad enough that they steal intellectual property all the time, but then to give it away to them, where it is a national security threat, potentially. How they could be thinking of doing this boggles the mind.

I will be getting a letter together, with anybody else on the committee that wants to sign on, please let me know, urging President Biden to drop this crazy idea of giving away—giving away—what is an American success story. We came up with multiple vaccines for a virus that we didn't even know in less than a year. Revolutionary. Never happened before that quickly, and safe and effective. And to give it away to China, it just boggles the mind.

Which brings me to the final point, Mr. Chairman. We ought to have a hearing in this committee on the origins of COVID–19. There may be other committees that might look at it, but as Mr. Jordan pointed out, this is the Select Subcommittee on the Coronavirus. And there are a lot of scientists out there suggesting that it may have actually come not from transmission between a bat and humans but potentially from the lab in Wuhan. We ought to know that. We ought to find out about that. We ought to do actual investigation and hearing to look into it, because we sure don't want this to happen again, but we also ought to know what really got us to this point, a point that caused hundreds of thousands of lives in America, millions across the globe. Hardship, heartache.

You still have millions of kids that aren't in school, against the science. We should have a hearing on that, because every school—we should be bringing school systems who are keeping the kids out of school right now in front of this committee and have them an-

swer about the science. Dr. Fauci, every doctor has said they should be in school, and, in fact, you are doing long-term harm to these kids by not having them in school, just to appease some union bosses who don't have the kids' best interests in mind. We will look back on this year later and say it was a national scandal that some of these systems kept millions of our young kids out of the classroom, and they will never catch up. That is something we ought to have a hearing on to.

But I appreciate the time we have had looking into this. Hopefully we can move forward. Mr. Chairman, with that I yield back.

Chairman CLYBURN. I thank the gentleman for yielding back. Let me close today's hearing by thanking Mr. Kramer and Mr. El-Hibri for your testimony and for taking the time to be here with us today.

As the coronavirus pandemic continues, the select subcommittee is focused on identifying shortcomings in our response and correcting them to ensure future success. In that spirit, we need you to do better. We need you to do a better job cleaning your facilities and training your staff. We need you to recognize that inspections by the FDA, your partners, and your own auditors are vital to helping Emergent be successful. And we need you to take their recommendations seriously and fix the problems they identify.

Accepting public funds requires upholding the public's trust. Emergent has wasted public funds and broken the public's trust. Mr. Kramer and Mr. El-Hibri, to repair this breach of public trust, Emergent must consider returning those wasted public funds. That includes the amount spent on doses that have been destroyed, on testing, and for the time you have wasted while production is put on hold, and problems were fixed. The errors that we have heard about today must never happen again. We have heard your promises, but what we need now is performance.

As I said in my opening statement, the select subcommittee's investigation is ongoing. This hearing is just the beginning. With Chairwoman Maloney's partnership, we will pursue this investigation until we understand why these terrible errors happened, and how they can be remedied, and what can be done to make sure they never happen again.

With that, and without objection, all members will have five legislative days within which to submit additional written questions for the witnesses to the chair, which will be forwarded to the witnesses for their response.

This hearing is adjourned.

[Whereupon, at 1:39 p.m., the subcommittee was adjourned.]