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EXAMINING MEDICAL PRODUCT DEVELOPMENT

IN THE WAKE OF THE EBOLA EPIDEMIC

WEDNESDAY, NOVEMBER 19, 2014

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:35 a.m., in Room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Burgess, Murphy, Blackburn, McMorris Rodgers, Lance, Cassidy, Guthrie, Griffith, Bilirakis, Ellmers, Barton, Capps, Green, Barrow, Castor, and Waxman.

Staff Present: Clay Alspach, Chief Counsel, Health; Brenda Destro, Professional Staff Member, Health; Brad Grantz, Policy

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Coordinator, O&I; Sydne Harwick, Legislative Clerk; Brittany Havens, Legislative Clerk; Carly McWilliams, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Alan Slobodin, Deputy Chief Counsel, Oversight; Heidi Stirrup, Health Policy Coordinator; Tom Wilbur, Digital Media Advisor; Ziky Ababiya, Minority Staff Assistant; Eric Flamm, Minority FDA Detailee; Hannah Green, Minority Policy Analyst; Amy Hall, Minority Senior Professional Staff Member; Karen Nelson, Minority Deputy Committee Staff Director for Health; and Rachel Sher, Minority Senior Counsel.

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Mr. Pitts. The subcommittee will come to order. The chair will recognize himself for an opening statement.

The world is currently experiencing the largest Ebola outbreak in history. The worldwide death toll is at least 5,177 people, according to the World Health Organization's November 14 situation report. Although the initial response to the Ebola outbreak was slow, it is now a top priority for the global public health community, including the United States.

At today's hearing, the subcommittee will examine an important aspect of the Ebola crisis, medical product development. As Ebola spreads, therapeutics are desperately needed to prevent, diagnose, and treat the disease. Federal agencies and drug and device manufacturers are hurrying to find treatments, vaccines, and diagnostics for this deadly disease. Adding to the frustration, none of the medications with the most promise are FDA-approved and therefore must be tested in clinical trials, which will take time.

In light of the Nation's substantial investment in public health emergency preparedness, many are wondering why no proven Ebola medications are currently available and what the Federal Government is doing to expedite their approval: Specifically, what is FDA doing to accelerate their review of products? How is BARDA assisting companies to prepare for clinical trials? What is the plan for manufacturing? And how and where will these medical products be

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distributed once they are approved or cleared?

Questions are also being asked about the administration's recent \$6.18 billion emergency appropriations request, including how much of the request is for development of medical products and how previous funding requests have been allocated and spent. I would like to thank all of our witnesses for being here today. I look forward to hearing your testimony.

And I will yield the remainder of my time to our vice chair, Dr. Burgess.

[The prepared statement of Mr. Pitts follows:]

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Dr. Burgess. Thank you, Mr. Chairman. And thank you for holding this hearing.

Thank you to our witnesses for agreeing to testify with us today. This is now number whatever of a series of hearings on the Ebola outbreak that this committee and other committees have conducted. As I mentioned yesterday in our Oversight Investigations Subcommittee hearing, one of the things that I think has become abundantly clear in dealing with this crisis is that all of us ought to bear a lot of humility because this virus is different from things we have seen in the past and doesn't always behave the way we expect it to, but this hearing today is not about looking at the past. It is looking at the future and looking toward additional lines of defense, vaccines and therapeutics and diagnostics to aid in the fight of this epidemic.

I can remember in medical school when I read that smallpox was over, that the last cases had been eradicated, and we would never have to deal with the illness again. And the way it was over was by a combination of epidemiologic studies and isolation, but also vaccination, so anyone who was exposed to the illness, the ring around them, the ring vaccination approach, was used so that any contacts were not just identified, but they were also vaccinated. And that did prove extremely effective in halting the progress of what at that time was a very terrible disease. And it wasn't in fact until I was elected to Congress that I realized that smallpox was in fact not eradicated,

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and we still had to be concerned about it.

But the point is that development of a vaccine will significantly aid in the fight against this illness. And for our aid workers and for our soldiers going to Western Africa to be on the front lines, we really do owe them the development of a vaccine so that they can feel protected as they, in fact, go forward to do good for their fellow humans.

I can't underscore the significance of people who are coming back who certainly want to know not only are they protected while they are away, but they are not bringing something back to their families, and particularly important I know to the men and women in the Armed Forces who are serving in Western Africa currently trying to help stem the flow of the epidemic.

I hope to hear this morning about the FDA utilizing a commonsense risk profile when evaluating diagnostics and vaccinations. On my visits down to Presbyterian Hospital the last couple of weeks, certainly I learned that the FDA was accommodating with hearing requests from people who were on the front lines of treating patients. For that, I am grateful. And I would like to hear what, going forward, what we can look to as far as help from the regulatory side.

Thank you, Mr. Chairman, for having the hearing, and I will yield back.

Mr. Pitts. The chair thanks the gentleman.

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[The prepared statement of Dr. Burgess follows:]

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Mr. Pitts. Now recognize the ranking member of the full committee, Mr. Waxman, 5 minutes for an opening statement.

Mr. Waxman. Thank you very much, Mr. Chairman.

The Ebola epidemic in West Africa is a devastating public health crisis. To date, more than 5,000 people have died from the disease and over 14,000 people have been infected, according to the Centers for Disease Control and Prevention. Many more cases are expected as this crisis overwhelms the affected countries' public health systems.

We have a responsibility to help end this outbreak, not only to help alleviate the suffering of those in West Africa but also to prevent this devastating illness from spreading further. And we must take actions now to prevent outbreaks like this from occurring again in the future.

Today's hearing will focus on one important piece of this goal, drug and vaccine development for treatment and prevention of Ebola. We need to look closely at why there are essentially no effective medicines or vaccines for this devastating illness.

In the United States, we rely on the pharmaceutical industry to discover, develop, and deliver new medicines to patients. This system works because there is a sufficient patient population that needs new medicines, our healthcare system can pay for the new treatments, and the industry can thereby recoup its investment. But Ebola is different. The need for the drug is sporadic. The U.S. patient

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population is almost nonexistent. And the countries with the most Ebola patients cannot afford to pay high prices.

So this is an instance in which the private market does not work. With Ebola, the Federal Government must drive the development of medicines by working with pharmaceutical companies. At our last hearing, we heard that the Federal agencies have indeed stepped up their efforts. The committee has also heard from companies with promising drug diagnostic or vaccine candidates who told us that the government has been acting as an effective partner. For our Federal agencies to continue to support the development of these products, Congress must provide increased funding now and ensure the stability of that funding going forward. That is why I support President Obama's emergency request. The request would provide the resources needed immediately to strengthen the ability of U.S. public health systems to respond to Ebola and address the current outbreak in West Africa. It includes over \$400 million for NIH, FDA, and BARDA, the Biomedical Advanced Research and Development Authority, to support the development, manufacture, and testing of Ebola diagnostics, therapeutics, and vaccines, and the request also sets the groundwork to strengthen global health systems to better prevent, detect, and respond to future disease outbreaks. Congress must act on this request promptly, but we also need to make sure that this isn't a one-time funding increase in the wake of an emergency. We should avoid a cycle in which we let our guard

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down once the immediate public health crisis passes and don't renew our efforts until the next emergency occurs and we find ourselves unprepared again. This kind of boom-bust approach to preparedness simply does not work. We must ensure that we establish a continuous operation and provide continuous funding so we are prepared for the next outbreak. I thank the witnesses for being here today and for your tireless efforts to help alleviate the suffering of those afflicted by the Ebola outbreak in West Africa.

Mr. Chairman, we need to do everything we can. At the minimum, we need to support the President's request so we can have this country do what is necessary in Africa and here at home to address this crisis. Yield back my time.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Waxman follows:]

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Mr. Pitts. I now recognize the vice chair of the full committee, Mrs. Blackburn, 5 minutes for an opening statement.

Mrs. Blackburn. Thank you, Mr. Chairman.

We now have about 15,000 cases and over 5,000 deaths in this 2014 Ebola outbreak. It is the worst since the virus was discovered in 1976, and we are hearing some good news out of Liberia, some mixed results out of the region. And in light of this outbreak, there should be an intensive effort to find and approve a treatment or, better yet, a vaccine to prevent Ebola. And Dr. Burgess has spoken so well about that and our concerns.

Now, the FDA and the FDA Priority Review Voucher Program was authorized by Congress in 2007 to incentivize the development for neglected tropical diseases. And although Congress did provide FDA with the ability to add diseases to this list through rulemaking, the process still takes time. That is why I have introduced H.R. 5729, which would add the filoviruses to the list of diseases included in the Priority Review Voucher Program. This family includes all known strains of Ebola as well as the related Marburg viruses.

And I want to recognize and thank my cosponsors on this bipartisan legislation: Representatives Green, Butterfield, McCaul, and Fleischmann. I also ask for the support of the rest of the committee members. This is an issue that needs and deserves our attention. And we stand ready to work with you. We welcome you as our witnesses today.

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And Mr. Chairman, I would yield the remaining time to whomever would like it.

Mr. Pitts. Does anyone seek time?

Mrs. Blackburn. I yield back.

Mr. Pitts. The chair thanks the gentlelady.

[The prepared statement of Mrs. Blackburn follows:]

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Mr. Pitts. That concludes our opening statements. Members' opening written statements will be made a part of the record.

We have one panel today. On our panel, we have today Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health; Dr. Luciana Borio, Director, Office of Counterterrorism and Emerging Threats, U.S. Food and Drug Administration; Rear Admiral Stephen Redd, senior adviser for Ebola response, Centers for Disease Control and Prevention; and Dr. Robin Robinson, Director, Biomedical Advanced Research and Development Authority at the Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.

Thank you for coming. Your written testimony will be made a part of the record. You will have each 5 minutes to summarize your testimony, and we will begin with you, Dr. Fauci, you are recognized for 5 minutes for your opening statement.

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STATEMENTS OF ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASE, NATIONAL INSTITUTES OF HEALTH; LUCIANA BORIO, M.D., DIRECTOR, OFFICE OF COUNTERTERRORISM AND EMERGING THREATS, U.S. FOOD AND DRUG ADMINISTRATION; REAR ADMIRAL STEPHEN C. REDD, M.D., SENIOR ADVISOR FOR EBOLA RESPONSE, CENTERS FOR DISEASE CONTROL AND PREVENTION; ROBIN A. ROBINSON, PH.D., DIRECTOR, BARDA, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF ANTHONY S. FAUCI, M.D.

Dr. Fauci. Thank you very much, Chairman Pitts, Vice Chairman Burgess, Ranking Member Waxman.

I appreciate the opportunity to address you today on the role of the National Institute of Allergy and Infectious Diseases in the research which is addressing our response to the Ebola virus disease epidemic. This particular effort -- interestingly, not fully appreciated -- actually began many years ago following the attacks on 9/11 at the World Trade Center and at the Pentagon, which the following month was followed by anthrax attacks through letters on the United States Congress and the press, which triggered a multi-agency government effort to address the medical countermeasures for

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bioterror. And as shown on this slide, there was a research agenda in which a variety of pathogens were identified to be the high-risk pathogens for bioterror attacks. And if you look on the bottom of the slide, there is anthrax, botulism, plague, smallpox, tularemia, but the viral hemorrhagic fevers are listed prominently there, including Ebola.

Years ago, we made the decision that not only would we need to be prepared for deliberate attacks in the form of bioterror but for the natural emergence and reemergence of these infectious diseases, so the biodefense agenda was merged into an agenda for naturally emerging and reemerging infections, and so the NIH put on a multifaceted effort that ranged from fundamental basic research through clinical research provision of resources for academic investigators and industries, with the result in mind of ultimately developing countermeasures in the form of diagnostics, therapeutics, and vaccines. And, as represented on this committee, what we had was a variety of agencies synergizing with each other. The NIH doing the concept and product, early product development, advanced development on the part of BARDA, which you will hear from Dr. Robinson soon, the commercial manufacturing, and finally the regulatory guidance and review by the FDA. Using this framework, we have products now that are in the various stages of the process of development.

I bring to your attention two that are most important, and that

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is Ebola vaccines in which we started the early phase I trials at the NIH on September the 2nd. We have completed enrollment and vaccinations. We have the early results of the product of the GSK Vaccine Research Center showing minimum adverse events and good immunogenicity. Soon behind that is the VSV or NewLink product, which entered phase I trials soon after the September initiation of trials at the NIH. And they are both now being studied at the NIH and by the Walter Reed Army Medical Center. There are a couple of others behind them, and we hope to begin Phase II/III trials for efficacy in West Africa by the very early part of next year, likely the first week or so in January. My deputy is currently in Liberia now determining the logistics of the trial.

In addition, there are therapeutics that are in development. Here is a list of some of them. I don't have time to go through all of them. But each of these in one form or another has been given on a compassionate basis to individuals who have been stricken with Ebola virus disease.

The one point I want to make to this committee is that we do not know if any of them work or how toxic any of them are, which really cries out for the kinds of clinical trials which we are currently designing to determine in a definitive manner safety and efficacy of these products.

I would like to close in the last minute to also bring to the

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attention of this committee that the NIH also has a special clinical studies unit at our clinical center in Bethesda. And we are designated, as shown on the map, as one of the three designated Ebola treatment facilities, along with our colleagues at Emory and at Nebraska. On the lower right is a picture of the clinical center, and you won't recognize me, but on the left-hand part of the slide is a picture of me as I was getting ready to go into the room to help take care of Nina Pham, who was a patient at the clinical center. And I am happy to say I think we already know that, as shown on this last slide, we were very happy and fortunate to have the opportunity to discharge her a couple of weeks ago. There is a picture of her on the left, and on the right is a picture of the nurses who helped us take care of her.

That is the end of my testimony, Mr. Chairman. I will be happy to answer questions later on.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Dr. Fauci follows:]

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Mr. Pitts. Dr. Borio, you are recognized for 5 minutes for an opening statement.

STATEMENT OF LUCIANA BORIO, M.D.

Dr. Borio. Good morning, Chairman Pitts and members of the subcommittee. Thank you for the opportunity to appear before you today to discuss FDA's response to the Ebola epidemic. My colleagues and I are determined to do all we can to help expedite the availability of safe and effective medical products for Ebola. The challenges posed by this epidemic are unprecedented, and the compassion and commitment demonstrated by the healthcare providers caring for patients with Ebola represent the best of humanity.

As you know, currently there are no treatments or vaccines that have been shown to be safe and effective for Ebola. The desire and need for specific treatments and vaccines are overwhelming, and we are taking extraordinary steps to speed the development, manufacture, and availability of these medical products. We are reviewing data as they are received. FDA took only a few days to allow vaccine studies to proceed. We are supporting the World Health Organization by providing technical assistance and advice on scientifically sound, ethical, and efficient clinical trials. We are working with our international regulatory counterparts to achieve regulatory harmonization and

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efficiencies in the review of investigational products for Ebola, and we are leveraging our authorities. We issued, for example, emergency authorizations for six diagnostic tests for Ebola.

Product development is proceeding at a very accelerated pace, and there is tremendous hope that some of these investigational products will help patients, but as Dr. Fauci just mentioned, these candidates are still in the early stages of development for Ebola. And it is possible that some may hurt patients, and others may have little or no effect. The fastest and most definitive way to assess their safety and efficacy is through properly designed clinical trials.

FDA is working with our NIH colleagues and investigators from the Emory University Hospital, Nebraska Medical Center to implement a flexible and innovative clinical trial protocol that would allow companies and clinicians to evaluate multiple investigational products for Ebola under a common protocol. This will create efficiencies. Our goal is to ensure accrual of interpretable data and generate actionable results in the most expeditious manner. Until such trials are established, we will continue to enable access to investigational products through special mechanisms, such as compassionate use. As you know, every Ebola patient in the U.S. has been treated with at least one investigational product. We have approved such requests for compassionate use within a matter of hours.

But just last week, WHO reviewed the data on the use of

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investigational products administered to patients under this type of mechanism. They found the data derived did not permit an evaluation of efficacy. This simply underscores the critically important need to establish properly designed and scientifically valid trials to determine whether these products help, hurt or have little or no effect. What we learn from these trials will have an impact on generations to come.

More than 300 FDA staff are engaged in response activities, and without exception, everyone has been proactive, thoughtful, and adaptive to the complex range of issues that we are facing. There is still a lot of work to do, but we are fully committed to this response. We will continue to leverage our authorities to the fullest extent to facilitate development and availability of safe and effective medical products for Ebola. And our decisions are always based on science, and I can assure you that we will continue to move as fast as the science allows. Thank you very much.

Mr. Pitts. The chair thanks the gentlelady.

[The prepared statement of Dr. Borio follows:]

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Mr. Pitts. Now recognize Admiral Redd for 5 minutes for an opening statement.

STATEMENT OF REAR ADMIRAL STEPHEN C. REDD, M.D.

Admiral Redd. Good morning, Chairman Pitts, Ranking Member Waxman, and members of the subcommittee. It is a pleasure to be here to have the opportunity to describe the current epidemic of Ebola in West Africa, what CDC is doing to respond there as well as here in the United States, and I will talk briefly about the work we are doing to support vaccine evaluation in West Africa.

Ebola, since its identification in 1976, is the same disease. The situation is very different in West Africa from prior outbreaks, but the disease itself is similar with the same symptoms, the same incubation period, the same spread through infected bodily secretions, and control measures that are being implemented to identify, isolate, and treat cases and track contacts. Although the purpose of this hearing is countermeasures, as we have heard, their availability can't be assured in the immediate future, so, for the near term, we are going to be applying those traditional public health measures.

I would note that the administration has requested \$1.83 billion for CDC to help respond to the Ebola outbreak. This is critical for three areas of work. The first is the immediate response in the

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affected countries, the highly affected countries, to extinguish the epidemic at its source. The second is to improve the ability in the U.S. to identify and treat cases. And the third is to increase the public health emergency response capabilities in vulnerable nations throughout the world, global health security agenda.

In West Africa, as we have heard, there are slightly more than 15,000 cases right now that have been reported, 5,700 deaths. These have been spread through two primary means, exposure to secretions through unsafe care, either in the community or in medical settings, and through unsafe burials. The situation is different in the three most highly affected countries, but I would note that even in Liberia, where we have seen signs of leveling off that there is still 200 to 300 cases being reported each week, so it is way too early to celebrate.

Two countries have controlled imported cases with stopping chains of transmission both in Senegal and in Nigeria. We are now working on a new situation in Mali. There are six cases that have involved two funerals and over 400 contacts that are being traced, and so we are very concerned about the situation in Mali right now. And with the end of the rainy season, there is increased possibility of spread to neighboring countries; particularly Cote d'Ivoire is a country of concern.

We used to say that this outbreak was bigger than all other outbreaks combined, but actually, in the past 2 weeks, there have been

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as many cases as there had been in all the previous outbreaks, and the current outbreak in West Africa is about 30 times larger than the largest previous outbreak.

I will turn now to U.S. preparedness. We have been working hard to prepare here before the first imported cases, and we have altered our plans as the situation has evolved. I will note just a couple of things that we have implemented. There is inbound screening of passengers that have traveled from West Africa to the United States in five airports. All travelers from those countries have to pass through these airports. Mali has been added to that list as of this past Monday. Those individuals are tracked for 21 days, their entire potential incubation period, so that if they do develop symptoms, they can be routed quickly to a place that can diagnose them and treat them.

I will turn now just briefly to countermeasure development. As Dr. Fauci mentioned, there are vaccine trials being planned for West Africa. CDC is planning to work collaboratively both with BARDA, FDA, and NIH on a trial in Sierra Leone using a different study design than the one that will be conducted by NIH. These are complementary and increase the chances of getting information on safety and effectiveness as quickly as possible.

I would just like to close with as long as there are cases in West Africa, there will be a risk of cases occurring in the United States. It is an important reminder that we are at risk when other countries

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lack basic capabilities. The administration's request underscores the urgent need to work in these vulnerable areas. I thank the committee for its interest in Ebola, and we hope to have your support with the emergency funding. That concludes my testimony.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Admiral Redd follows:]

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Mr. Pitts. Now recognize Dr. Robinson 5 minutes for an opening statement.

STATEMENT OF ROBIN A. ROBINSON, PH.D.

Mr. Robinson. Good morning, Chairman Pitts, Vice Chairman Burgess, Vice Chairwoman Blackburn, and Ranking Member Waxman, and distinguished members of the subcommittee. Thank you for the opportunity to speak with you today about our government's Ebola response efforts. BARDA, created by the Pandemic and All-Hazards Preparedness Act in 2006, is the government agency with the full-time responsibility to support advanced development and procurement of novel and innovative medical countermeasures, such as vaccines, therapeutic drugs, diagnostics, and medical devices for the entire Nation. I am here today to update you on the progress that we have made on Ebola medical countermeasure response activities.

BARDA has used several overarching principles to guide us through previous public health emergencies, like the H1N1 pandemic, H7N9 outbreaks in China last year, and is now applying them to the current Ebola epidemic response. First, BARDA exists to address the medical consequences of biothreats and emerging infectious diseases. Ebola represents both.

Second, BARDA works with our Federal partners here to transition

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medical countermeasures from early development into advanced development towards ultimate FDA approval. Today BARDA has transitioned one Ebola therapeutic candidate and three Ebola vaccine candidates from early development in NIH and DOD into advanced development with three more therapeutic candidates and one more vaccine candidate under consideration.

Third, BARDA in concert with our Federal partners, utilizes public-private partnerships with industry to ensure that we have countermeasures to protect our citizens. Today we are working with both small and large biotechnology and pharmaceutical companies in public-private partnerships and collaborating with other countries and NGOs and providing actually staff to help WHO in their efforts.

BARDA, fourthly, has established a medical countermeasure infrastructure to assist product developers on a daily basis and to respond immediately in a public health emergency. To name a few, today BARDA is utilizing our nonclinical studies network to conduct critical animal challenge studies to evaluate new Ebola monoclonal antibody and therapeutic candidates; our Centers for Innovation in Advanced Development and Manufacturing to expand production of Ebola monoclonal antibodies as they become available; our fill-finish manufacturing network to fill both Ebola antibody and vaccine products into vials; our new Clinical Studies Network to help CDC plan and conduct vaccine clinical trials in Sierra Leone early next year, as Dr. Redd said; and

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our modeling unit to coordinate Federal and international modeling efforts for evolving Ebola epidemiology and interventions. These investments that you and we have made since 2010 to create this infrastructure are now playing a major role in the Nation's response to the current Ebola epidemic.

Lastly, BARDA supports large-scale production of medical countermeasures as a response measure for public health emergency. Today BARDA is working with our industry partners to scale up production of Ebola vaccines and monoclonal antibodies to ensure commercial scale manufacturing will be possible when needed. Specifically, we have implemented a three-pronged approach to maximize the production of promising Ebola monoclonal antibodies, like ZMapp. First, we awarded a contract in September to Mapp Biopharmaceuticals for development and manufacture of ZMapp produced by Kentucky Bioprocessing using tobacco plant-based technologies. This product candidate has been provided to non-Ebola infected persons under EID with FDA's assistance. Efforts to optimize production have already seen a nearly twofold increase in production yield, and the clinical trials for this product are on track to start in January 2015 being conducted by the NIH.

Because the present manufacturing process is at pilot scale, we are expanding manufacturing capacity by enlisting the help of other tobacco plant biopharmaceutical companies, including those associated with ADMs.

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Lastly, we are trying to increase antibody production by partnering with several companies, including Genentech and Regeneron, who make monoclonal antibodies at commercial scale routinely for other diseases and have developed innovative state-of-the-art monoclonal antibody technologies and mammalian cells. We are on track now to test these three, test new Ebola antibodies early next year in animals and, if successful, in human clinical trials shortly thereafter. Additionally, we will weigh the results of ongoing NIH animal challenge studies to determine whether we support advanced development of two Ebola antiviral drug candidates.

With respect to vaccines, BARDA is supporting the development of several vaccine candidates from Profectus for clinical trials next year and NewLink Genetics for product development and commercial scale-up manufacturing. With additional funds, we will be able to support commercial manufacturing scale up and further clinical trials for other promising Ebola vaccine candidates from GlaxoSmithKlein, Johnson and Johnson, Bavarian Nordic to ensure we have vaccines when they are needed.

Finally, together, we face significant challenges in the coming weeks and months as the Ebola epidemic evolves, clinical trials start, and manufacturing improvements are implemented. Be assured, we are doing all that can be done, and I thank you for your help over the years, and I look forward to your questions. Thank you.

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Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Robinson follows:]

***** INSERT 1-4 *****

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Mr. Pitts. That concludes the opening statements.

I have a UC request to put in the record a letter from Novavax and an article from the New England Journal of Medicine.

Without objection.

[The information follows:]

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Mr. Pitts. I have one more. An article by Andrew von Eschenbach and Paul Howard, entitled "How to Upgrade Ebola Fight."

Without objection, so ordered.

[The information follows:]

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Mr. Pitts. I will begin the questioning and recognize myself for 5 minutes for that purpose.

Dr. Robinson, the President's request for emergency Ebola response funding includes \$157 million for BARDA for immediate response to manufacture vaccines and therapeutics. The request does not specify or specifically mention if any of these funds would be used for the development of rapid diagnostic tests to identify Ebola. Of the \$157 million that was requested in emergency funding, how much do you plan to dedicate for the development of such tests?

Mr. Robinson. Thank you for the question, Chairman Pitts. BARDA actually has funds in its ARD program for diagnostics and will be using those funds for development of diagnostics, as many of these diagnostic devices will have applicability not only for Ebola but for other biothreats.

Mr. Pitts. Okay. To all the panelists, I understand that HHS has reached out to the private sector, which includes a company from my home State of Pennsylvania, in order to expedite medical countermeasure products. How have companies responded to your request? We will just go down the line. We will start with Dr. Robinson.

Mr. Robinson. To date, we have 152 different companies that have come to BARDA and gone through our TechWatch program, telling us about what their product candidates can do and not do. And we have either

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asked them to submit proposals or directed them to our colleagues at NIH or even FDA and CDC and DOD if funding is more directed toward discovery and early development. So we have had a robust response at this point.

Mr. Pitts. Admiral?

Admiral Redd. We receive a number of requests each day, about 20 per week. We generally, for most of those, route them either to BARDA or to NIH or to FDA, depending on the particular issue. We have had, apart from countermeasures, we have had a very vigorous interaction with the private sector on the donation side. It has been very helpful in our response in West Africa.

Mr. Pitts. Dr. Borio?

Dr. Borio. We have quite a bit of interest from companies. We direct them to the appropriate review divisions to explain the process. We are clearly prioritizing those companies for which NIH, BARDA, and DOD are supporting. We also had quite a bit of interest from the diagnostic industry. We did a lot of outreach for them and to explain the EUA process, and that has also paid off because we have now seen increased interest incoming through the FDA for the development of diagnostic technologies.

Mr. Pitts. Dr. Fauci?

Dr. Fauci. Very similar, Mr. Chairman, literally a couple per day that get directly referred to us as well as secondary referrals

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from the FDA or CDC or BARDA when they go to them, and then they send it to us. We have a division in my institute where we have one component of it that essentially spends full time working with industry trying to sort out the things that we can help bring forward for them or things that we might essentially say are not really relevant to what we are doing. Most of them have a positive aspect that we pursue, sometimes immediate, and sometimes it is going to take a year or so to work it out, but we are very, very closely involved with industry in this.

Mr. Pitts. Thank you.

Dr. Borio, PAHPRA strengthened FDA's current emergency use authority and provided the agency more flexibility to get products to the public in an emergency. I was glad to see the FDA issue an EUA last week for a diagnostic test related to the ongoing Ebola epidemic. Would you please provide more details on the agency's use of these new authorities for Ebola? Are there more tests or therapies that may become available soon to healthcare workers on the front lines?

Dr. Borio. Well, I can't underscore how important the new authorities have been for us to be able to respond as fast as we have, specifically with the diagnostics. Since the first EUA was issued back in August for the DOD-developed test and that, again, we were able to do that because of these new authorities, and they were critical to be able to put diagnostics in West Africa as well as rapidly deployed within the laboratory response in our work at CDC. We will continue

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to make use of those authorities as needed.

Mr. Pitts. Is FDA currently examining utilizing trial designs that would ensure that all participants receive the vaccine?

Dr. Borio. So, Dr. Fauci, would you like to discuss the clinical trial designs for vaccine?

Dr. Fauci. Yes. We feel very strongly, Mr. Chairman, that in order to definitively determine the safety and efficacy of a vaccine which you will, after all, be giving to normal healthy people, that you have to have a trial in which not every single person gets the vaccine at the same time because if that is the case, you will never know whether a vaccine works. We are doing a randomized control trial in Liberia. The CDC will be doing what is called a step wedge trial in Sierra Leone. I just want to point out to the committee that if there were calls back about a month or two ago of distributing the vaccine widely in West Africa without a control group, had we done that, the downturn in Liberia now would have been attributed to the vaccine when, in fact, it was a downturn, and there was no vaccine. So that is the reason why we have got to be careful to make sure we have a control group.

Mr. Pitts. Thank you. My time has expired.

The chair recognizes the ranking member, Mr. Waxman for 5 minutes of questions.

Mr. Waxman. Thank you, Mr. Chairman.

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Earlier this month, the administration requested \$6.2 billion to enhance the U.S. Government response to the Ebola outbreak. The request included \$400 million for NIH, FDA, and BARDA to support the development, manufacture, and testing of Ebola diagnostics, therapeutics, and vaccines.

Dr. Borio, how would FDA use the additional funds in the administration's budget request to advance diagnostics, therapeutics, and vaccines to deal with Ebola?

Dr. Borio. Well, thank you. So since --

Mr. Waxman. Could you speak a little louder or right into the mike?

Dr. Borio. Sure. So more than 300 FDA staff have been involved in this response, and they represent tremendous scientific expertise to be able to support this robust pipeline of Ebola products. They have been working full time, all hands on deck, at a very accelerated pace to be able to sustain, and part of the reason why we would be able to respond so rapidly is because of the recent support that this Congress has given us in the last few years through the countermeasures initiative.

Now, to be able to continue to sustain the aggressive response that we think we will need in the foreseeable future, we do need additional resources to hire additional staff so that we can continue doing what we are doing and see the results that we are seeing.

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Mr. Waxman. Thank you. Dr. Fauci, give us a brief overview of how NIH would use the funds included in the request for your agency.

Dr. Fauci. Thank you for the question, Mr. Waxman.

We, the NIH, of the amount that you mentioned, is asking for \$238 million. That will be divided into -- for example, one big chunk of that is \$56 million to conduct the Phase II-III trial, the randomized control trial in Liberia, and there is a certain amount to do the secondary and tertiary candidates should that candidate fail, and then there is a chunk of money to go for diagnostics and therapeutics. We have, as Dr. Borio mentioned, a common protocol to test all of the therapeutics that you saw on that list there in one way or another. That takes tens of millions of dollars to do those kinds of trials. All of that together is the \$238 million request from the NIH.

Mr. Waxman. I was recently at a conference where people were looking at the ideas for faster cures, getting new therapeutics out to people right away. And they said that if they could eliminate some of those trials that FDA now requires and get their product out faster, it would lower the price and save people's lives. And one person even argued, why not let the individual make the decision how much of a risk they are going to take. How would you respond to that idea?

Dr. Fauci. I would disagree with that completely, Mr. Waxman, because having had considerable experience in the testing of therapeutic agents and vaccines, I think there is an assumption and

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an understandable emotional desire when you have a lot of pain and suffering to just give medications to people. There are a couple of things wrong with that. First of all, experience tells us that a substantial proportion of those might turn out to not only be not effective but might actually be toxic. And the thing you learn as a physician on your first day in medical school is, first, do no harm. And despite the dramatic nature of the situation, we really need to determine if they work, and that is the reason why our common protocol allows us to determine whether something is safe and effective.

Mr. Waxman. Well, thank you.

To support the clinical trials as well as more widespread use of any therapeutics and vaccines that are proven to safe and effective, we will need to be able to quickly increase their production.

Dr. Robinson, can you discuss how the emergency funding request would help BARDA support expanded manufacturing for promising therapeutics and vaccine candidates.

Mr. Robinson. Yes, sir, Mr. Waxman. We are funding right now the commercial scale production at NewLink to going forward with that to be able to produce at, instead of tens of thousands of doses, hundreds of thousands or even millions of doses going forward. Additionally, with funding that has been requested we would be able to do that with also GlaxoSmithKlein and even J&J and Bavarian Nordic.

On the therapeutic side, we certainly are doing that with ZMapp

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right now by expanding other production facilities and going a different way with the what we call CHO cell, mammalian cell production with the other manufacturers and to produce those new antibodies and then be able to have those made at commercial scale so we could have thousands of those treatment courses available immediately.

Mr. Waxman. Mr. Chairman, if you will allow me, I wanted to ask Dr. Redd, there is a \$621 million for CDC for the domestic response. Can you describe how you plan to use these funds?

Admiral Redd. Yes, sir, thank you. The work would support the ability to improve what we are doing now, identifying cases, getting them to treatment rapidly. So it would provide funding for laboratory development, for improving workforce capacity, improving biosafety, improving hospital infection control, and assuring that personal protective equipment is available for the staff that are providing care to these patients.

Mr. Waxman. Okay, thank you.

Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

Now recognize the vice chair of the full committee, Mrs. Blackburn, 5 minutes for questions.

Mrs. Blackburn. Thank you, Mr. Chairman.

And, again, thank you all. This is something we have got to get a handle on, and I think you probably realize from listening to our

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questions, our constituents are very frustrated with the way that much of this has been approached with the lack of -- seeming lack of preparedness that our Federal agencies had, even though they had been hearing about this for months, and then, of course, the fact that our U.S. military, my constituents from the 101st, had to be sent over to build hospitals and to train medical workers. So it is good to hear that you all are engaging the private sector and that you are beginning to work forward on this.

Dr. Fauci, you referenced the slides at the beginning in your testimony. You know, you mentioned the length of time that you all had focused on this, going back to 2001. I would like to encourage you, during that time, time doesn't equal results, basically. And the slow movement of the bureaucracy in preparing to address these category A situations that you outlined is frustrating. And it does show a lack of flexibility. So that flexibility is going to be important going forward, and it is something Congress is going to hold you accountable for.

The private sector moves at a faster pace.

And, Dr. Robinson, I was pleased to hear you say that you are engaging with the private sector as you are seeking a way to move forward with this.

Let me ask you, do you have any, Dr. Robinson, any American pharmaceutical companies that have, in accordance with FDA's IND

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program, Investigational New Drug Program, sought emergency export provisions and requested recognition from HHS that an emergency situation exists in West Africa that warrants the export of an IND that could be helpful in fighting Ebola?

Mr. Robinson. Not to my knowledge, but I would ask my colleague Dr. Borio to help with that.

Dr. Borio. So this provision has been used to export ZMapp to Liberia, this export provision. And there has been interest expressed by additional companies to export investigational product to Liberia using this export provision, and we are currently working with HHS and the companies to --

Mrs. Blackburn. Okay. So, Dr. Borio, I am like Mr. Waxman, I can hardly hear you. It is very difficult to hear you here on the dais. So you are saying that only one company, ZMapp, has requested recognition?

Dr. Borio. No, I am saying that this provision, this export provision has been used by one company, ZMapp, to get the product to Liberia at the request of the Liberian government.

Mrs. Blackburn. Okay. So you all have approved only one, and the only one you have approved is ZMapp?

Dr. Borio. This provision does not -- one company has met the requirements for the export provision, and the product was exported to Liberia. We have received interest and questions from additional

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companies about how to make use of this export provision, and we are working with HHS --

Mrs. Blackburn. Okay, let me interrupt you then. How long does it take through this to get recognition, for a company to get recognition? Because my understanding is there are other companies that are there, and I do have the letter from the Liberian Ambassador that was dated October 22nd, seeking other options, therapies, and drugs to move forward in this program. So how long will it take you all through this program? Dr. Borio or Dr. Robinson, either one, what is the estimated time that it will take somebody to get through this program?

Dr. Borio. So for products that are under review at FDA for which we have substantial information already in the product, we are able to move very fast, and we are working hard to resolve the situation for the products for which we have very little information, but our intent is to be able to support export a product when the company is --

Mrs. Blackburn. Dr. Borio, I hate to interrupt you again. What we are looking for is a time frame. You know, are you talking about 1 month, 2 months, 6 months? What do you anticipate? How much energy are you going to put into this to save countless lives? How quickly do you think you can move this forward? That is what we are looking for is more of a time frame, please, if you can.

Dr. Borio. I appreciate the intent of moving investigational

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product to those countries. I would just -- I don't know that to save countless lives -- we do not have information on these products' safety and efficacy. Our intent is to support the request of Liberian or West African governments to receive investigational product and our intent of course is to support companies that are interested in exporting product and --

Mrs. Blackburn. I need to interrupt you. My time has expired, but I am going to ask you to please submit in writing a timeline, an orderly process timeline that will give us an idea of how quickly you anticipate these products are going to be able to be available for emergency export.

I yield back.

Dr. Borio. Thank you.

Mr. Pitts. The chair thanks the gentlelady.

Now recognize the gentlelady from Florida, Ms. Castor, 5 minutes for questions.

Ms. Castor. Thank you, Mr. Chairman.

Thank you all for being here today and for everything you are doing and your teams are doing to combat the Ebola threat and especially containing and stopping the threat from West Africa.

And Dr. Fauci, last time you were here, I mispronounced your name, and I apologize, and I will not do it again.

The ongoing Ebola threat in West Africa is a reminder of the

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importance of drug and vaccine development when it comes to fighting these viral threats and the key role played, our leadership here in America, the key role played by the U.S. Government. While Americans are bombarded by advertisements for various pharmaceuticals because we have an open and competitive marketplace for drugs in America, Ebola is entirely different. Development of therapeutics and vaccines for Ebola and similar diseases is entirely driven by government activity because the market for these treatments is small and sporadic and because affected countries cannot pay high prices for these drugs, and yet there is a lot at stake. We tend to pay attention to the U.S. Government's role in times of crisis, but we have got to constantly look ahead to foresee potential medical threats long before they appear. So I would like to hear, Dr. Fauci and Dr. Robinson, how do your agencies identify which infectious diseases and biological hazards are top priorities? How do you anticipate what the threats of the future are?

Dr. Fauci. Well, we can start off by saying that it is impossible to accurately predict what the next outbreak will be. You can have a pretty good idea that looming there in the background is the possibility of there being a pandemic influenza. And that is what we prepare for continually. We are trying to improve our abilities vis-a-vis influenza vaccines, particularly our effort in trying to develop a universal flu vaccine that you don't have to make every time

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you get a new strain, as opposed to what we literally have to do every year when we change strains as the virus drifts, and sometimes, with a pandemic, it would shift.

Regarding something like Ebola, which started off in our mind as a threat of bioterror and then, as I mentioned in my opening statement, became a potential threat of a natural emergence because we have seen it emerge 24 times since 1976, The way you prepare for that is to do the kind of research, fundamental basic clinical research, to develop countermeasures.

I might bring up also the question that Ms. Blackburn asked about how long it took to develop an Ebola vaccine. We had been working on that since 2001, 2002, and we were kind of like the lone wolf on that. We could not get industry even slightly interested in that. So although they can turn out to be quicker than the government, they did not want to step up to the plate. And it was only just literally a year or so ago that we got the first big company to partner with us, which is the reason why we have a vaccine right now. So we were looking around very aggressively to have partners in industry and could not find one, which is one of the reasons, if not the reason, why we don't have a further advancement on our vaccine effort right now.

Ms. Castor. Dr. Robinson?

Mr. Robinson. So the other part to that is that the prioritization of biothreats and then other manmade threats is done

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through our Department of Homeland Security providing material threat assessment determinations, and then the Public Health Emergency Countermeasure Enterprise actually goes through a prioritization -- in our strategic implementation and implementation plan that came out in 2012 and is being updated this year -- actually goes through that prioritization process. Right now, you know everything that have been threats are highly there, except the ones that we have actually been able to make medical countermeasures, such as botulinum antitoxins and to a certain extent with our anthrax and smallpox medical countermeasures, what we have actually been able to make great progress through those. But the others are still there, and they still have all high priority.

As Dr. Fauci said, these product candidates were early in development and as they have progressed, and if we had not had any outbreaks, we would have been picking up normally several of these anyway, but because of that, now we have actually moved forward to help the industry compress the time frame to be able to develop and produce these vaccine candidates and therapeutics from 2 years or 3 years down to a year and a half and maybe even 12 months. And so, by working together, we are actually able to do that with our colleagues at FDA and NIH.

Ms. Castor. Thank you.

My time has expired.

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Mr. Pitts. The chair thanks the gentlelady.

Now recognize Dr. Burgess 5 minutes for questions.

Dr. Burgess. I thank the chairman for the recognition.

Dr. Fauci, let me just take a minute again and thank you for taking care of our nurse, your patient, Nina Pham. It was incredible to watch the press conference and see her conveyed back home to her family that was waiting and just appreciate everything you did to assist her in her recovery.

I mean, I will speak to some of the same frustration you have heard up here this morning, and I so appreciate the fact that there is a vaccine that was on a clinical trial. In fact, I think I was in Mr. Pitts' district for a field hearing in August. And the head of GlaxoSmithKlein was there and talked about literally next week we are going to start this clinical trial. And I am grateful for that. I appreciate the difficulties they have in getting the vaccine to the country because of the technical considerations surrounding the care and feeding of that vaccine and how it has to be stored, but even the acceleration by 1 month of the Phase II clinical trials, going from January to December, with the rapidity with which this disease is striking down people in Western Africa, I mean, that 1 month could translate into hundreds, if not thousands, of lives, so that is -- yes, the country has made a significant investment in getting us all to this point, but we are anxious to move beyond where we are right now because

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it does seem that we have arrived at this point in history without the tools, and Dr. Fauci, not a criticism, but just a question as far as -- and I appreciate your statements on randomized clinical trials, and I realize those are the gold standard under which we all live, but for people who are self-identified as traveling to Western Africa, who voluntarily would like to receive a vaccine prior to going, is there any mechanism for them to be part of those clinical trials?

Dr. Fauci. The answer is yes because in the Phase I trials, a certain proportion of them have been actual healthcare workers predominantly. I think if you want to get into now the Phase II or III, depending upon whether you are in Sierra Leone or you are in Liberia, if you sign up for a trial, you will be assigned to one or the other of a limb of a trial. If it is a randomized control trial, it will be double blind; you won't know what limb you are in. If it is a step wedge, it is a different design that sort of phases in different groups, so there really depends on the trial itself.

I do want to point out, Mr. Burgess, that when you are talking about a vaccine, as you well know from your experience, it is different than a therapy for someone who is sick. When you are dealing with a vaccine, you are dealing with giving it to a normal person, who can do many other things to avoid getting infected in the sense of the personal protective equipment, et cetera. When you are dealing with a therapy for a person who is already sick, that is when you get the

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compassionate use approach that the FDA has been quite flexible in granting for the therapies.

Dr. Burgess. Let me just ask a question of anyone on the panel, and maybe the CDC is the best person to ask the question to. How many people -- are there any persons currently under treatment in any of the Ebola facilities in this country, or have all those persons been discharged or unfortunately died?

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[11:30 a.m.]

Admiral Redd. I believe, at the current moment, there are no patients in any of the units in the U.S.

Dr. Burgess. And, Dr. Borio, you remember we had a hearing I was allowed to attend on the Foreign Affairs Committee in September, and the concern came up about a clinical hold on one of the therapeutics that was under development.

Where are we today with releasing that compound from a clinical hold?

Dr. Borio. Federal law and FDA regulations preclude me from discussing specifics about the product in question. I have asked the company permission to disclose specifics, but the permission was denied.

And but what I can tell you, because it has been reported by the company itself, is that development of product may continue in patients who are infected with Ebola. And to my knowledge, development has not been hampered by the partial clinical hold in healthy volunteers.

Dr. Burgess. And so that drug is then available for compassionate use in an Ebola patient?

Dr. Borio. The drug is available for compassionate use in

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patients with Ebola and for clinical studies in patients with Ebola.

Dr. Burgess. And how -- at the FDA, how are you going about evaluating the risk profile of therapeutics given the high mortality rate of this illness?

Dr. Borio. So, clearly, it is very important to take into consideration the seriousness of the disease and to be able to properly evaluate the potential benefits and the risks, and that is what our expert reviewers and team of urologists, pharmacologists, our toxicologists will do for every product.

Dr. Burgess. And I hope you are prepared to share some of that information with us. As time goes by, I think that would be extremely useful.

And, Mr. Chairman, let me just say, of course, we have got the Cures Initiative also going on in the background, and many of the lessons learned with how drug development has occurred or the regulatory effect -- or the effects of the regulatory agencies on drug development I think can be instructive for us as we work through the Cures Initiative. So, again, I hope you will be willing to come back and share that information as we go through this process.

Dr. Borio. It would be my pleasure.

Thank you.

Dr. Burgess. Thank you, Mr. Chairman.

I yield back.

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Mr. Pitts. The chair thanks the gentleman.

Now recognize the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman, and I appreciate you having the hearing today, and I want to thank our witnesses for testifying.

While we are seeing some progress in response to deadly Ebola virus, much needs to be done in the months ahead to keep Americans safe and develop much needed vaccines and treatments.

Dr. Borio, I want to thank the FDA, because we deal with them -- we have dealt with them as long as I have been on this committee. I understand that the FDA has been given -- has given 24 hours' notice to some of the Ebola patients that has come into our institutions and on possible, you know, drugs to be able to cure it, and I just appreciate the FDA with that kind of quick response and -- because, again, if you are at that level, you know, people will be able to say, "Well, do whatever you can." And I appreciate the FDA; 24 hours is really great, and that is what I have heard from the medical personnel.

You may be aware that a bipartisan group of colleagues and I, Representatives Blackburn, Butterfield, and McCaul, have introduced a bill to allow the FDA to add Ebola to the FDA's Priority Review Voucher Program. This program was authorized in 2007 to promote the development of new treatments and vaccines for neglected tropical diseases. Our legislation would add Ebola to the list of eligible

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diseases, creating a new tool to advance the development of new treatment and vaccines.

Do you believe that this sort of incentive might encourage further private investment in this effort?

Dr. Borio. I don't know that it would, but we remain interested in working with Congress and any incentives that may help develop these products. And in the meantime, we will continue to do all we can to provide those incentives, including, for example, we did recently an orphan drug designation for one of the products to -- as an incentive. So we think that it is important, clearly, for products such as these to have as many incentives as we can.

Mr. Green. Do you know of any other incentives that might be useful in attracting further private sector investment and vaccine research in the development for Ebola or other infectious diseases.

Dr. Borio. I would be happy to give it some thought and I will get back to you if I --

Mr. Green. Okay. I appreciate it, and thank you.

Dr. Fauci, in earlier testimony you talked about the linkage between the Ebola drug and vaccine development and the National Institute of Allergy and Infectious Disease. And I am glad our government and the private sector is stepping up to the challenge in developing vaccines and other treatments for Ebola. I want to make sure we are also paying attention to other tropical diseases that are

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emerging.

In my City of Houston and elsewhere along the Gulf Coast, we held a 21st Century -- I take that back. We held a 21st Century Cures roundtable in Houston recently. Chagas disease is one example of what is known as a neglected tropical disease. It has caused serious heart disease and even death if left untreated. While no one in Houston has contracted Ebola as of yet, several Houston residents have been diagnosed with Chagas, and recently these were not people who had travelled outside the U.S. to places where Chagas is widespread. In the past, NIH has supported regional centers of excellence in emerging infectious diseases, but the neglected tropical diseases was never a significant aspect of that initiative.

Would you be willing to work with me and the committee to find a way to support similar regional centers of excellence in these neglected tropical diseases?

Dr. Fauci. We certainly would take that into consideration, Mr. Green. In fact, you are referring to my good friend Dr. Peter Hotez, who is there now running that effort with Chagas disease. He was formerly here at GW, and we have had a very close collaboration with him, and I would be more than happy to sit down with you and him and talk about the possibilities in this regard.

Mr. Green. Glad to, and I know Dr. Burgess was at that meeting, so was our colleague in the Houston area, Congressman Olson, and be

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glad to work with you.

Mr. Chairman, that is all the questions I have, and I yield back my time.

Mr. Pitts. The chair thanks the gentlemen.

Now recognize the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. Murphy. Thank you, Mr. Chairman.

Dr. Fauci, it is my understanding that some enrolled in vaccine trials will be given placebos, of course. Can you discuss any ethical dilemmas this is going to create, and if there is a plan to treat those individuals who may receive the placebo?

Dr. Fauci. The trial of a randomized control, double blind trial, is a classical paradigm for the determination of the safety and efficacy of vaccines. It has gone through the strictest ethical review --

Mr. Murphy. I understand that. I am just referring to -- I don't question that. I just want to make sure that things are in place to monitor closely and treat those who may still show up with systems, either with the vaccine or without the vaccine.

Dr. Fauci. Absolutely.

Mr. Murphy. I want to present some of the concerns raised yesterday during the hearing that I chaired in Oversight investigation.

When we heard from Ken Isaacs of Samaritan's Purse, the group's

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doctors and medical aid workers have been in West Africa fighting the outbreak for a long time. He noted, like other health experts, that there is a lot of unknowns with Ebola and, of course, pointed out that, for example, 95 percent of Ebola cases incubate within 3 weeks and then emerge, but as a New England Journal of Medicine article noted, 5 percent may not emerge until some 42 days later.

We have heard there has been some 341 mutations of the virus. This obviously underscores there is a lot we don't know about Ebola, and we need to be humble about that.

So other things Mr. Isaacs raised was that what would happen if this continues to spread; Africa and other portions of India were some of the key features.

Now, in a book that Dr. Friedan recommend I read, "House on Fire," about smallpox, at that time, when they started to use the vaccines, it was also very vigorous on isolation. So much so the way they contained people was they even put guards around the homes of those with smallpox, would not let them travel anywhere, and made sure no one came in contact with them.

So in order to -- in moving forward on this, do you see any move forward in terms of dealing with restrictions and containment in the villages in Africa and also travel to the United States as part of this?

Dr. Fauci. Well, they are two separate issues, Mr. Murphy. One is a patient who is sick with Ebola. Those patients, by routine

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protocol, go into strict isolation. So that is not a problem.

When you are dealing with an asymptomatic person who you are suspecting might have Ebola, that is a different story. Unlike smallpox, we know that you do not get Ebola unless you come into direct contact with body fluids --

Mr. Murphy. Not true, because there have been cases where people have been wearing the personal protective gear but have still gotten Ebola. There have been cases where people have been asymptomatic but have had positive tests. There is people who have been symptomatic and have negative Ebola tests. So I want to stop you because you have, in the past, made condescending statements about people who talk about the what-ifs.

Doctor, we are in the business of what-ifs. You are in the business of what-ifs as a clinician, as a scientist, and so are we. We have to ask these questions. And I am deeply, deeply concerned if we continue down this path of arrogance and hubris in saying, "We got this," because we don't.

Because it was also pointed out in "House on Fire," if smallpox came again to the United States, just one case would send people into a panic. We want to help here. And I am pleased that you are moving forward vigorously and the FDA is moving forward vigorously on these vaccine trials, but I also want to make sure that -- there is going to be billions of people who don't have the vaccine. And as we are

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moving forward on this, I want to make sure that we are doing all we can to maintain a high defense perimeter so that people who have been exposed Ebola are not traveling throughout Europe and the United States without other restrictions.

Now, in yesterday's hearing, it almost sounded like, in some ways, that people are spiking the ball that we don't have cases in the United States. But let's face it, we will have more, and I want to make sure that we are following up.

I mean, New York City is saying they want \$20 million just to deal with the one case and tracking 500 -- dealing with 500 people there. So these costs are going to go up.

So a long way of getting to this point, I want to find out, are you going to continue to coordinate the vaccine trials along with other aspects of quarantining, of looking at travel, of dealing with travel issues, so this does not spread to other people who don't have the vaccine?

Dr. Fauci. The answer is yes. We will do everything within the scientific data that we know, the experience and the realization that there are things that we don't know to do the things that you say.

Mr. Murphy. Well, with regard to the scientific data, how many cases would it take to overwhelm the system in the United States today?

Dr. Fauci. I can't give you a number on that, but certainly if we have a major outbreak, the kind that we have --

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Mr. Murphy. We only have like 10 bed spaces. Right?

Dr. Fauci. Well, we are --

Mr. Murphy. I am not talking about thousands of people getting it. My point is, let's continue to be humble about this. Let's continue to understand there is a lot we don't know and move forward and work as a team on this. We want to help, but I want to just make sure that we are not just telling people, "We got this and everything's fine at this point." We still have a lot we have to learn.

I recognize my time is up, and I yield back.

Mr. Pitts. The chair thanks the gentleman.

Now recognize the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. Lance. Thank you, Mr. Chairman, and good morning to the distinguished panel.

You have mentioned in your testimony that this is an unprecedented global health crisis, and over the course of the past several months, there has been widespread confusion over hospital best practices, travel protocols, and even treatment options. The distinguished panel sits before the committee today representing four distinct agencies that have been tasked with addressing the crisis. I would ask the members of the panel, how can we ensure that there is no overlap or redundancy in your work?

Dr. Fauci.

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Dr. Fauci. Well, when you talk about overlap, we do have mandates and missions that are -- I believe are synergistic and not overlapping or duplicative, and I try to explain that on the slide that I showed. If you look at the NIH's responsibilities for the development of concepts, fundamental basic and clinical research to try and understand the disease and develop the early part of the development of the countermeasures. So you have BARDA, who is involved in the advanced development. You have CDC, whose main mandate is the surveillance and disease control as opposed to the development of countermeasures as we do, and you have the FDA as the regulatory agency. So I think it is a pretty good flow of synergy, as opposed to overlap and duplication.

Mr. Lance. Others on the panel?

Dr. Borio. I will just add that we all have our roles, and we work very, very closely together, and we talk several times a week, several times a day sometimes. We have each other on speed dial. So I believe that we are doing everything we can to move in synergy and not duplicate each other's work.

Mr. Lance. Thank you.

Admiral Redd. I am probably going to say what you have already heard, but I think that the two things are there are specific lanes of effort, but where there are borders or interfaces, we work very closely to make sure that the work we are doing is supportive rather than unnecessarily duplicative.

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Mr. Lance. Thank you.

Dr. Robinson.

Mr. Robinson. Yeah. I mean, this is not our first time at this. We have done this from H1N1 to H7N9 last year and now this year, and have built up that infrastructure to talk with one another and to actually know what our budgets are and what are strengths are where we can actually tap into one another.

Mr. Lance. Thank you.

Regarding the point you raised on budgets, has the panel been asked or your agencies been asked to provide information to the administration regarding its recent funding request?

Dr. Fauci. That is how the budget was developed, actually. We were asked by the administration to make a proposal for what we felt was necessary for us to accomplish our mission to address the Ebola outbreak in West Africa, as well as here potentially in the United States, and each of us submitted a budget proposal, which then ultimately went forth after review at the administration level to the Congress, where we testified a week or so ago to the Appropriations Committee.

Mr. Lance. Others on the panel, you were involved in the budget request? Others?

Admiral Redd. Yes, along with OMB to coordinate the request through the Department.

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Mr. Lance. Dr. Robinson?

Mr. Robinson. Absolutely.

Mr. Lance. Thank you.

Have you developed action plans specifying how and where the money would be spent if it is approved?

Dr. Fauci. When you make -- yes, sir. When you make a budget proposal, you have to delineate each of the line items. For example, as I mentioned in a response to a question from Mr. Waxman, the NIH request is \$238 million. So it just wasn't a bulk request for 238. There was \$56 million for the performance of Phase II-III trials. There was \$76 million for this and \$23 million for that. So they were line item by line item.

Mr. Lance. And is that true of the other agencies as well?

Dr. Borio. It is for us.

Admiral Redd. Yes, sir.

Mr. Robinson. Absolutely.

Mr. Lance. Thank you.

I think it is important for the public to know as we move forward in the appropriations process as to how the money will be spent and where the money will be spent. And certainly we want to work together in a cooperative fashion in our oversight role, and I certainly wish all of you well as we overcome this tremendous health challenge, not only to this country but really to the entire world.

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Thank you very much, and I yield back the balance of my time.

Mr. Pitts. The chair thanks the gentleman.

I would like to apologize to the gentlelady from California. I didn't notice you come in.

I would like to recognize the gentlelady from California, Ms. Capps.

Mrs. Capps. Thank you, Mr. Chairman.

I want to take one minute to sing the praises of my professional colleagues, nurses, because nurses have really been at the front lines of the Ebola response, both domestically and abroad. And I want to take a moment to highlight their service.

Unfortunately, this also means that some nurses have been infected during their selfless care for other people. The two nurses infected in Dallas highlighted the important concerns about the effectiveness or non-effectiveness of existing training and guidelines for U.S. healthcare workers treating Ebola patients.

I was pleased to see the CDC issue new guidelines October 20th calling for better training and equipment and adopting practices successfully in place now at hospitals at Nebraska Medical Center, Emory, and the NIH. I think we can all agree we wish they had come out sooner. It is critical, however, that the CDC continue to be a leader in setting guidelines to protect our healthcare workers and contain the spread of Ebola.

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So, Dr. Redd, since the adoption of the CDC's new guidelines, what has the reaction from hospitals been? Given that guidelines issued by the CDC are voluntary, do you see that hospitals are cooperating in the implementation of these stricter measures?

Admiral Redd. I think the reaction has been extraordinarily positive. That has been seen in the number of people that have participated in training in the use of the new guidelines, in the responses we have gotten from the visits that we have made to hospitals through States to work on hospital preparedness.

I think the one concern is the availability of personal protective equipment, something that we are working on shoring up, but that is probably the major concern.

Mrs. Capps. I want to follow up with that topic because I visited two hospitals in my district, and PPE, or the personnel protective equipment, has had such a surge in demand following -- and particularly now following your guidelines, in addition to growing demand by other entities worldwide, and what can we do to help with the PPE supply so that -- is CDC -- and can it ensure the availability of it? Are you working on that?

Admiral Redd. Yes, ma'am. I think there actually are different efforts that have different time horizons. It is -- part of our budget request is for personal protective equipment. In the short term, we want to be sure that hospitals that would be treating patients have

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a supply that is sufficient for a short term --

Mrs. Capps. Right.

Admiral Redd. -- and then there is an ability to acquire personal protective equipment from distributors, from the community, and then there is a supply in the strategic national stockpile that can shore up. So a layered approach to be sure that there is personal protective equipment available for the care of the patient.

Mrs. Capps. And that is -- the administration's request for \$6.2 billion to enhance the government's response, is that critical, then, you see to this being able to be carried out?

Admiral Redd. Yes, ma'am. It is a part of that request.

Mrs. Capps. Good. And I could -- just anecdotally -- and the hospitals that I visited in my district corroborate that getting supplies is really high on their minds at that level, as well as the designation of some regional hospitals so that -- as you have said, we are going to see more cases, Dr. Fauci, you mentioned. We need to be ready for them.

I wanted to turn to Dr. Borio, and with respect to the FDA, we all, of course, when this outbreak occurs, wish there were more effective treatments and vaccines already available. And we have heard there are several companies at work on such medicines, but they are not yet ready. Your testimony mentioned some of the hurdles that drug developers face. Would you discuss this in a little deeper depth?

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Dr. Borio. So, for these types of products for Ebola, I see two major challenges for developers. One has to do with the fact that the pre-clinical work has to be done -- most of it has to be done in high containment BSL-4 laboratories. So, by default, this is going to be a public/private partnership. Nobody can really go at it alone.

And, for subsequent phases, as we are witnessing now with this epidemic, the clinical testing is quite challenging because these outbreaks tend to occur sporadically in unpredictable fashion and in areas of the world where very limited healthcare infrastructure. And that has to be built up a little bit before clinical investigations can take place. So these are pretty two large hurdles for the --

Mrs. Capps. Absolutely. I am running out of time, but I wanted to know if you are trying any of the products on people yet? Is there -- have we reached that stage?

Dr. Borio. So we are working with NIH and investigators in Nebraska and Emory to be able to establish the common clinical trial protocol to be able to most effectively and expediently evaluate our safety and efficacy. They are not quite in the phase of clinical investigations yet. All the use has been done under compassionate use.

Mrs. Capps. Okay. Thank you.

Mr. Pitts. Chair thanks the gentlelady.

And now recognizes the gentleman from Louisiana, Dr. Cassidy, 5 minutes for questions.

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Dr. Cassidy. This is a great panel. I apologize, as I will ask your questions to be concise, otherwise there is just no hope I will get through my 20 minutes of questions.

Dr. Fauci, it is implied, but not explicitly stated, are the antibodies elicited neutralizing?

Dr. Fauci. Yes. The antibodies that we --

Dr. Cassidy. What is the window period between exposure to vaccine of the virus and antibody development?

Dr. Fauci. Later than usual. It probably takes, I would say, at least 12 days into the course, and maybe 7 or 8 days following the initiation of symptoms before you see good IGM and IGG responses.

Dr. Cassidy. Now you -- and you say good, but is it detectable -- good pre-supposes a certain titer, but can you see low titer, perhaps nonprotective, at some point prior to that?

Dr. Fauci. You do, but it is very, very low, and you don't --

Dr. Cassidy. Okay. I am sorry.

Dr. Fauci. -- couple of days.

Dr. Cassidy. I am sorry. Now, you mention that the only way to determine -- and I am all for case control trial -- excuse me, for double blind studies. But it does seem to me having a mortality rate approaching 50 to 90 percent, you can actually differentiate between a downturn because of good infection control and that which is due to vaccination by looking at antibody titers.

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If somebody is -- if you have a less prevalence of disease and there is no antibody markers, it is clearly a case it is infection control. It is not subclinical cases in something which has 50 to 90 percent mortality. Is that a fair statement?

Dr. Fauci. Right.

Dr. Cassidy. Now, Dr. Jenner, way back when he did cowpox for smallpox, I am always stuck, did not do a double blind study. He just basically saw he gave cowpox vaccine, and there was less smallpox. There was a mortality rate of 25 percent. So the efficacy was quickly recognized.

Now, knowing that you have plenty of lead-in time to do a case control analysis of a population to see what is the background of certain incidences, it does seem to me that you could do a study which would be single arm or maybe just different doses of vaccine, but which would have a case control, if you will, of a historical control as opposed to one which must be double blind.

Dr. Fauci. I disagree with you, sir, because if we had done that a couple of months ago, which we were criticized for not doing, why don't we just go out and let the vaccine out following Phase I, if I had done that in September and October, the downturn in Liberia would have been ascribed to the vaccine.

Dr. Cassidy. No, you would have looked at antibodies, and you would have seen that there was a decreased prevalence of antibody

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production.

Dr. Fauci. With all due respect, sir, you are talking about someone who is infected and has an antibody response. You know they are infected. You don't need an antibody response to tell you that.

Dr. Cassidy. But let me ask you, is it subclinical cases, or is it the absence of infection that has caused the downturn?

Dr. Fauci. Downturn in antibodies?

Dr. Cassidy. You said in Liberia, there is a few -- there is less prevalence of disease.

Dr. Fauci. Correct.

Dr. Cassidy. Now, that -- was it subclinical cases, or is it the absence of infection that has caused this --

Dr. Fauci. I don't know what you mean by subclinical cases.

Dr. Cassidy. As in people who are exposed to the virus but do not get sick.

Dr. Fauci. Yeah. When you say exposed, do they get infected. There is a difference. You can get exposed and not get infected. If you are infected --

Dr. Cassidy. If you mean exposed and not infected, then, my gosh, we are actually doing something good there.

I am assuming that there is a -- not splitting hairs, but let me just construct it this way. If somebody has exposure to the virus, is infected in some way, but it is subclinical, they will have still

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have antibody titer.

Dr. Fauci. Right.

Mr. Murphy. Now, we can look at a downturn in infection, we know it is either due to less transmissibility and people actually getting infected; it is due to an increased number of subclinical cases; or in the case of a vaccine, it might be that vaccine was protective.

Dr. Fauci. Right.

Mr. Murphy. So it seems like the antibody titer would give you clues as to whether or not it is the vaccine giving beneficial effect or whether it is a decrease in infection rate.

Dr. Fauci. Well, there is one premise that you said that I don't accept, and that is that there are subclinical infections. The --

Dr. Cassidy. In that case, it makes it simpler, because if there is no subclinical infections, that means that if there is a downturn prevalence of disease, it is either the vaccine or it is infection control.

Dr. Fauci. It is infection control. There is no doubt in my mind that it is infection control.

Dr. Cassidy. Okay. That is a fair statement.

Now, it does seem as if we could give the immunization in a single arm study, and we could compare it to historical controls.

Dr. Fauci. But how can you compare it to historical controls if, while you are doing it, the infection rate is going down? You have

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a changing scene as you are doing the trial.

Dr. Cassidy. Does the vaccine elicit IGMs?

Dr. Fauci. It does.

Dr. Cassidy. Oh, it does?

Dr. Fauci. It does.

Dr. Cassidy. Okay. And -- well, let me revisit that and let me go on to Mr. Robinson.

I am struck by, Dr. Robinson, I am struck by the amount of money that is being requested. And it does seem as if, for example, the CDC is already getting \$716 million for global control, global -- \$416 million for global health, and it is getting \$1.3 billion for public health preparedness and responsiveness on the State level.

Presumably, this money is over on top that. It seems like the same programs could be repurposed to accomplish this goal. Obviously, we are in a time of fiscal constraint. Is the fiscal constraint -- my gosh, this is a lot of money. Why can't we use the money we already have, knowing that we want to do everything we can, but is what we have adequate to do what we need to do?

Mr. Robinson. So, with the \$157 million that BARDA requested in the President's budget request --

Dr. Cassidy. I am looking specifically at the global health. That is what I have been before. The global health is getting \$416 million now.

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Mr. Robinson. That is Dr. Redd, not --

Dr. Cassidy. Yeah. I am sorry.

Admiral Redd. Yes, sir. We are using that money. This money would be requested to --

Dr. Cassidy. I accept that, but you already have money. Can it not be repurposed for that -- why do we need additional? Can you not repurpose what you have already received?

Admiral Redd. Well, that money is -- let me -- I think that it probably is a question that needs to be answered more specifically than I am going to be able to right now in terms of what those funds are being used for now and what the new funds would be used for.

Dr. Cassidy. Well, how many PPEs are we purchasing?

Admiral Redd. With the funds that we have right now, we have purchased -- our aim is to have enough PPE for --

Dr. Cassidy. But how many is that?

Admiral Redd. It is enough to take care of --

Dr. Cassidy. Is it a million? Is it 100,000? Is it 60,000?

Admiral Redd. \$2.7 million, and that is enough PPE for 250 patient days of care.

Dr. Cassidy. Okay. It seems like a lot.

Admiral Redd. It is expensive.

Dr. Cassidy. Okay. I am out of time. I yield back. Thank you.

Mr. Pitts. Chair thanks the gentleman.

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And before I recognize Brett Guthrie, just mention that this morning announcements were made, and our vice chair, Dr. Burgess, will chair the new committee chairman, taking Lee Terry's place. And Brett Guthrie will take his place as vice chairman of the health subcommittee. So look forward to working with you.

Mr. Guthrie, you are recognized 5 minutes for questions.

Mr. Guthrie. Thank you, Mr. Chairman.

I really enjoy -- thank you for those comments, and will enjoy working with you as well.

I want to, Dr. Robinson, I represent central Kentucky. I have Owensboro, which is Kentucky BioProcessing, and I have watched them for quite a while using tobacco plants. Of course, what we are talking about was ZMapps not Kentucky Burley, but using tobacco plants is good. And it is something that we have been real pleased to see develop in our area. And just was there last month with Leader McConnell to get an update after the ZMapp stories had come forward. And the production of ZMapp through a plant-based process is a little time consuming and led to a recent shortfall of doses. It necessarily wasn't in their plan to have all this out there ready because they were still in trials, but it is my understanding there are currently about 80 doses of ZMapp available and more being produced. And I know that BARDA is working on a final decision --this is my question -- on increasing ZMapp production and the final decision is due soon. Do you have an update

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on that decision of increasing ZMapp production?

Mr. Robinson. Yes, sir. Back in September, we actually awarded Mapp Biopharmaceutical, which subcontracted to Kentucky Bioprocess in the production of six campaigns or six lots of ZMapp product. They have finished the first one. I am not sure 80 is exactly the right number, because we actually -- it may be a little less than that, but the second campaign is going well, and that is why I reported today that we saw almost a twofold increase in product yield. In the succeeding lots, we think that we will see even more improvement.

Going forward, I mean, the funding that we have asked for is actually to help them do more improvements all across the board in the manufacturing process such that they can have more product available sooner.

The product they are making right now that actually has been in the first campaign will be in the first clinical trial studies that the NIH will be doing.

Mr. Guthrie. Okay. Thanks.

But I -- and I would ask that as you make sure that proven, manufacturing processes are considered into all routes of the production, are there other people doing it, and I know this has been a proven manufacturing process, and not put all of our eggs in one basket.

I do want to talk about the funding, and this is -- I know it is

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within your budget. We have an infrastructure capable of developing, testing, and producing medical counter measures with partners. We just discussed ZMapp, which is a positive example of products in the system's pipeline. And I also understand that promising vaccines are being scaled up and will be manufactured commercially.

And what is BARDA's strategy to pay for this? You testified 2015 funds were only sufficient until December of 2014, which is right around the corner, and the commercial production of ZMapp would not be possible in that lifetime. The White House has asked for \$6 billion in emergency requests, and only \$175 million for BARDA, barely enough for a fraction of these efforts. So can you outline how you are going to scale these manufacturing processes up for these products within that limit?

Mr. Robinson. Yeah. Well, it was \$157 million was in our request, and we want to thank Congress for providing \$58 million already to us in the continued resolution anomaly. So we already have that money, and we actually have used that, not only for ZMapp, but also to go forward with the development of new Ebola --

Mr. Guthrie. Is this new request going to be sufficient to scale up the --

Mr. Robinson. Yes. Not only for the therapeutics, but also for the vaccines with the proposals that we actually have in hand with the manufacturers and are negotiating and will be announcing soon.

Mr. Guthrie. Okay. I am going to ask you one more question,

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then.

It is my understanding that authority over all BARDA contracts is controlled by the Office of Acquisition Management Contracts and Grants and the Office of the Assistant Secretary of Preparedness and Response.

When we have heard from medical countermeasures, MCM, developers that this cumbersome arrangement has created confusion, unnecessary delays and uncertainty. Regarding the time sensitive review of BARDA's medical countermeasures developing contracts, would you prefer if BARDA was allowed to negotiate, manage, and award its own advance R&D contracts as it has done in the past?

Mr. Robinson. So BARDA originally did actually have the contacting authority -- the contacting shop in its -- in 2009, the contracting office was moved over to the Office of the Assistant Secretary for Preparedness and Response. Going forward, we would consider any actions that would help expedite the review and execution of these accounts.

Mr. Guthrie. My understanding we moved the money back but not the authority. So the statutory authority is still in the other -- you would like to have that authority back?

Mr. Robinson. We would consider that and many other efforts that go forward. Whatever would work, actually.

Mr. Guthrie. But it would speed up development of processes if

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you did or critical medical countermeasures?

Mr. Robinson. It might, but I will say, though, that our contracting shop has done Herculean efforts in a number of different public health emergencies, including H1N1, where they actually moved contracts extremely fast. So I think they are very able.

Mr. Guthrie. Well, that was my question. You wouldn't be able to do this without having to have this other step in the process. You think you are capable and able to do that, and you prefer to do it without the other --

Mr. Robinson. I think they are capable, and are actually doing that right now with the Ebola epidemics.

Mr. Guthrie. Thank you. I appreciate that, and I yield back.

Dr. Burgess. [Presiding.] Gentleman yields back.

The chair recognizes Mr. Griffith 5 minutes for your questions, please.

Mr. Griffith. I appreciate it, Mr. Chairman.

I did note with some interest just a minute ago Mr. Guthrie mentioned that ZMapp's being grown in a tobacco plant. He said it wasn't the Burley that he grows in his district. My district grows all kinds of tobacco, and if you all need more plants grown, I got a bunch of farmers know how to grow tobacco and can do it very efficiently.

That being said, the Pandemic and All Hazards Preparedness Reauthorization Act requires the FDA to finalize its guidance to

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industry regarding the development of animal models to support the approval, clearance or licensure of countermeasures. Of course, clarifying how these products may be tested in animals is critical to developers as human trials are rarely possible. In March of this year, FDA requested an additional 6 months to finalize this guidance.

Dr. Borio, when do you expect this important guidance to be finalized?

Dr. Borio. It is very important to finalize this guidance. On the bright side, I have to say that the guidance has been well accepted by industry and academics. It is in circulation. We had a lot of consultation prior to putting this guidance together, and we are moving as if this guidance is final, but it is very important, I know, to finalize it. It is a priority for us.

Mr. Griffith. All right. I appreciate that.

Do you have any estimate of time? Six months? A year?

Dr. Borio. I would like to finalize it as fast as I can.

Mr. Griffith. Yes, ma'am. I appreciate that. Thank you.

Dr. Fauci, I understand that several thousands of Ebola viruses samples cannot be transported to NIH, CDC and other government labs in the U.S. because the CDC on behalf of the U.S. Government has not reached agreements with the countries of origin to permit the shipment and research of the samples. I would also note that, on November 5th of this year, Reuters reported U.S. Ebola researchers plead for virus

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samples.

I would have to assume that the NIH has a strong interest in getting these Ebola virus samples out of West Africa and over to NIH labs and other government labs. Am I correct in that?

Dr. Fauci. Yes. It is important for us to get samples to be able to examine them and do the appropriate genomic sequencing.

Mr. Griffith. And that way, you can have a better idea of whether or not it is mutating and how fast it is mutating. Isn't that correct?

Dr. Fauci. Correct.

Mr. Griffith. And they also would be helpful in creating diagnostic tests. Is that correct?

Dr. Fauci. Well, certainly you want to match the virus to the diagnostic tests and vice versa.

Mr. Griffith. And likewise, you want samples from as many of the countries affected as you can get, particularly Sierra Leone and Liberia because they have -- or may have different strains. Is that correct?

Dr. Fauci. Well, I am not saying different strains. It could possibly be -- when you say different strain, that is a big difference. The strain is the Ebola Zaire strain. There may be some slight modifications depending upon mutations, but it is not going to be a different strain.

Mr. Griffith. Okay. And I used -- that is what happens when you

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are a country lawyer trying to mess with medical terms, but what you are after is to see if it is mutating and what is going on --

Dr. Fauci. Correct.

Mr. Griffith. -- is that correct?

Dr. Fauci. Correct.

Mr. Griffith. And so if you only get it from one area, you may not be able to see all the mutations that are occurring. Is that accurate?

Dr. Fauci. You are absolutely correct. You need a wide range of isolates from different places.

Mr. Griffith. All right. And what is the biggest concern about mutations in the Ebola virus? And obviously, I know that, you know, how much more contagious is it is or how much more deadly it is, but what can you tell me about that as well as those obvious ones.

Dr. Fauci. Yeah. From a practical standpoint, something that is feasible is that it could mutate and make the diagnostic tests a little bit less sensitive, or when you make a vaccine that would make a particular response against a virus, it may not be as avidly binding to the virus when you are looking for protection.

There is always out there this issue, is it going to change so much that it dramatically changes its modality of transmission, namely, what you have read about in the newspapers about becoming a respiratory borne virus? Certainly, that is not impossible, but that is a very,

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very unlikely scenario, simply because in the history of viruses, it is -- really would be unprecedented that a virus, by mutation, would completely change the method by which it is transmitted. So although we always look for that and keep it up as a possibility, it is unlikely. It is more likely that it would have some impact on the accuracy of the diagnostic test.

Mr. Griffith. And let me ask about that, and it is probably too early for you to answer, but is that possibly one of the concerns with the doctor that was recently brought back to Nebraska, that originally the tests indicated he didn't have the disease, and then later it was clear that he did -- he was symptomatic when they did the test, but he didn't test positive. Now, I understand there are always errors and mistakes and things happen, but is that one of the concerns that --

Dr. Fauci. It is, sir, but I think it is something more likely, because we have experienced this before, it is likely that it wasn't that there was anything wrong between the match between the test and the virus but that when he got his first test, his level of virus was so low in his body that the test wasn't sensitive enough to pick it up. And when you wait a couple of days the way they did, they got a positive test. So there was no problem with the diagnostic test. It was likely that his level of virus was doing this and then started to go up. So when they did the first test, it might have been quite low, and then when they did it a few days later, it was high enough

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to pick up.

Mr. Griffith. And how many days was it, because I thought I had read somewhere that it may have been close to a week.

It was 4 days.

Dr. Fauci. Four days.

Mr. Griffith. All right. I see my time is up, and I appreciate your answers.

And I yield back.

Dr. Burgess. Gentleman yields back.

At this time the chair now recognizes the gentlelady from North Carolina, 5 minutes for questions, please.

Mrs. Elmers. Thank you, Mr. Chairman.

And thank you to our panel for being here on this issue. I know we are all very motivated to move forward on treatments and cures, vaccines for Ebola and certainly so many other diseases.

And I just want to say right off the bat that I had the pleasure of hosting a 21st Century Cures initiative roundtable discussion in my district. And Dr. Robinson was kind enough to come to it and attend. It was very well attended. It was wonderful information that we accrued, and it basically all had to do with vaccines, and it was right about the time that the Ebola situation was really starting to come to the forefront. So it has now become so timely.

I do want to start off by asking Dr. Robinson a question, and this

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gets back to the funding request of \$157 million, and I just want to make sure that we all understand the process.

When the initial trials are being run and when there is a drug that is being investigated, looked at for success, it is still in the NIH space. Is that correct?

Mr. Robinson. So NIH will fund a preclinical study, and then the transition in the Phase I studies is when NIH funds that, and then we go with the subsequent studies afterwards.

In parallel to that, though, there is the development of the vaccine, the vaccine manufacturing process, the analytical tools actually be able to lot release the vaccine and to be able to do the subsequent Phase II and Phase III --

Mrs. Ellmers. So there is a little bit of a simultaneous, you know, between BARDA and --

Mr. Robinson. We hand off, actually, and I can give you other examples with other vaccines, which we actually do this, where we actually handle the manufacturing, and the NIH handles the Phase 1 clinical studies. Again, looking at our strengths, so that then it is a seamless transition as it goes forward.

Mrs. Ellmers. And I guess that is the question. What I am looking for is I want to make sure that there isn't necessarily a clear stopping point and then BARDA comes in so that we can actually be moving forward.

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So, keeping in mind the funding request, how many vaccine candidates do you believe BARDA will be able to support when we look at this, and I know we have been talking about a few numbers, but what -- if you could give us a --

Mr. Robinson. So, with the funding request that we have, we will be able to provide funding for four vaccine candidates of the five that NIH has and DOD have supported previously.

Mrs. Ellmers. Five of -- okay. So four --

Mr. Robinson. Four of the five.

Mrs. Ellmers. Four of the five. Okay. And then to the question, too, and, there again, this is just me trying to understand the process. So, from that point on, will HHS be the purchaser of the Ebola vaccine?

Mr. Robinson. So at such time that a decision has been made, when we know that the vaccine is been well tolerated, that the vaccine works, and that there is real need to do so, then HHS will be certainly one of the purchasers of the vaccine. There will be others, including GAVI, that will actually mobilize the overall global effort to purchase vaccines.

Mrs. Ellmers. Okay. Okay. Thank you.

Dr. Fauci, I would like to ask a little bit about some of the public-private partnerships that NIH and the private sector have been undergoing with the Ebola vaccine, especially when we are talking about

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the medical countermeasures against the threat.

How can you describe to us the National Institute of Allergy and Infectious Disease moving forward? What can we do a better job working with BARDA that, you know, that National Institute of Allergy and Infectious Disease can work better with BARDA? Is there something that we can do to move that process forward in a more efficient manner?

Dr. Fauci. Yeah, Mrs. Ellmers, I don't think so. We work pretty well, not only on Ebola -- as Robin said, we have done this movie before. We did it with pandemic flus. We did it with regular flus. We did it with MERS and SARS, et cetera. So we have a long history of working pretty well interdigitated between ourselves and BARDA.

Mrs. Ellmers. Great. So you feel very -- I mean, you feel very confident in the process as it is right now, then, as far as that?

Dr. Fauci. Well, we always can do better, --

Mrs. Ellmers. Right.

Dr. Fauci. -- but -- I don't want to go on the record for that, but I can tell you that I feel pretty good about how the interaction between BARDA and FDA and ourselves has gone.

Mrs. Ellmers. Working very well.

Dr. Fauci. And the CDC, because they are involved in the front end with it.

Mrs. Ellmers. Right. Exactly.

Okay. I have just a moment. Well, I will tell you what. I am

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just going to stop there because I think my line of questioning would be too lengthy, and, again, I just want to say thank you all of you for being here on this issue.

Dr. Burgess. Gentlelady yields back her time.

The chair recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for your questions, please.

Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it very much.

And I appreciate the testimony by the panel today, and I have a couple questions.

I recently held a roundtable in my district to discuss Ebola with local officials and first responders. I wanted to see if they received the training and resources available to adequately diagnosis and, of course, treat any infected patients.

During the roundtable, a few questions came up, and I wonder if I can get a response.

Admiral Redd, I was told the CDC had only designated one lab in Florida. I represent the Tampa Bay area, and the lab, apparently, is located in Miami to verify possible cases of Ebola. They were concerned that this might be impractical since it is impossible to transfer potentially infected blood by mail. Will more labs be allowed to verify cases specifically in my State of Florida, and why was Miami chosen?

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Admiral Redd. So thank you for the question.

The laboratories that are -- that CDC works with to do the reference diagnostic test for Ebola are part of the Laboratory Response Network. So those laboratories have training in a wide variety of diseases, and so that is the group that CDC has worked with.

As far as transport, in general, that is handled by courier rather than mail to get the specimens as quickly as possible to a laboratory that can do the test that has all of the quality control and the sensitivity that is necessary.

Mr. Bilirakis. So there are no other labs that qualify in this instance in the State of Florida?

Admiral Redd. I am not sure if there is another Laboratory Response Network laboratory in Florida. I could get back --

Mr. Bilirakis. Can you please get back to me on that?

Admiral Redd. In general, the State health laboratory --

Mr. Bilirakis. It is a huge State, as you know.

Admiral Redd. Yeah, do that test, and so there are a limited number in the country, as you noted.

Mr. Bilirakis. Thank you.

This is for the panel. President Clinton and President Bush both had a special assistant for biodefense on the National Security Counsel. That individual ran an annual simulation for pandemic influenza and graded agency performances. I was an original

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co-sponsor of legislation in a previous Congress to create a permanent special assistant position.

Would a permanent special assistant position for biodefense allow for better coordination in planning for future outbreaks, and for the panel?

Admiral Redd. I think the system that we have in place now is working very well. So I think that is -- that would be -- that would be my personal recommendation. I don't think we have a policy on that.

Mr. Bilirakis. Do we have a clear figure in command?

Admiral Redd. Mr. Klain is the coordinator across all of the government for the response. He works on the policy issues and is really helping to identify the things that need to be done and make sure they get done as quickly as possible.

Mr. Bilirakis. Does anyone else want to give their opinion on that?

Dr. Fauci. If you exclude Ebola and talk about just how we handle things in general, and then I will mention, as Steve did, about the current Ebola response coordinator, the ultimate responsibility for that is in Homeland Security. So the Homeland Security advisor, Lisa Monaco, and that is the reason why, early on in the epidemic, when we were talking about the White House coordination, it was with Lisa Monaco. Then when it became clear that this was a full-time job, that she had other responsibilities, and that is the reason why we then

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brought in Ron Klain, who is the Ebola response coordinator, because this became a full-time job, and -- but, in general, prior to Ebola and likely after Ebola, it will still stay at the level of the Homeland Security.

Mr. Bilirakis. Okay. Next question for the panel, again, is there a national biodefense plan for future outbreaks? Who would like to respond first?

Dr. Fauci. It is part of the second slide that I showed was the bio defense agenda still holds true, and it involves multiple agency. It involves ASPR, which includes BARDA, FDA, CDC, and NIH, and that is just for HHS. We also have collaborations with the Department of Defense and the Department of Homeland Security. So that was developed soon after 9/11, and that agenda still holds true.

Mr. Bilirakis. So there is a plan in place?

Dr. Fauci. Yes.

Mr. Bilirakis. Anyone else want to comment on that?

Mr. Robinson. So the National Health Security Strategy is being updated -- I think it is every 2 years -- but that has already been put into place, and that is where we actually -- these action plans can fall down from or cascade down from.

Mr. Bilirakis. Okay. Thank you very much.

I guess my time -- I have got about 4 seconds. I will yield back. Thank you.

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Dr. Burgess. Gentleman yields back his time.

I am just going to ask a couple follow-up questions. I ask unanimous consent to do that.

Without objection, so ordered.

Dr. Fauci, that was a fascinating exchange between you and Dr. Cassidy, and I actually enjoyed that very much. It was one of the most instructive 90 seconds that I have seen on this committee in the 10 years that I have been here.

But it did raise a question in my mind. It is pretty much -- well, not -- shouldn't say that, but the use of convalescence serum, for example, in Brantly's case, hard to know whether that was what really helped or not, but it seems to be attractive enough that it is continuing to be used, but does the use of convalescence serum in any way cloud the antibody picture that then you have to look at when you are reconstructing responses to this illness?

Dr. Fauci. The answer is no. It doesn't cloud it, because the circumstances, Mr. Burgess, that you would use convalescence serum is someone who is sick and you are trying to bring the level of virus down. So it doesn't matter if it clouds the ongoing endogenous IGM and IGG response to the person. That becomes almost irrelevant because it is clear that that response may not be adequate to suppress the virus without help. So the convalescence serum is someone who has already hopefully peaked.

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Now, one of the problems that we are facing in evaluating convalescence serum is that it isn't a static level of antibody. It goes up, and it comes down. So if you transfuse convalescence serum late in the game, you may not have very good tiers. So one of the things we are trying to do in the broad study of convalescence serum is to make sure we titrate it and know exactly what we are giving to someone, as opposed to guessing that this person might have a high titer and this person might have a low titer. So that is one of the questions that we are addressing.

Dr. Burgess. So you are attempting to quantify it?

Dr. Fauci. Yes. Exactly.

Dr. Burgess. And then, Dr. Borio, does that require compassionate use? Does the FDA need to give approval for the use of convalescence serum?

Dr. Borio. So, today, the use of convalescence serum in the U.S. has been done under compassionate use.

Dr. Burgess. So all of those cases that have been treated in the United States hospitals have been compassionate use?

Dr. Borio. Yes. And I just wanted 2 seconds with regard to -- you know, there are major questions about the benefit of convalescent plasma, and, again, it just underscores the importance of doing proper clinical investigations because we do not want to come into the next outbreak, you know, with the same questions we have today

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about the benefit of convalescent plasma because it is a laborious type of therapeutic to administer.

Dr. Burgess. Let me just ask you, and this, of course, is something that weighs heavily on my mind, having been in north Texas when the outbreak occurred. I mean, I share everyone else's concern about travel and restrictions, but what really keeps me up at night is that unknown person who is going to walk in the back door of an emergency room in any of our communities across the country, and the entire cascade of events that happened in Dallas could be revisited.

Do you think we are any better prepared, or have we informed people? Do you think there is better awareness, or are we still just as vulnerable as we were on September 25th?

Dr. Fauci, yes, sir.

Dr. Fauci. I think there is a big difference now. The awareness of the importance of a travel history, I think, is now -- should have been embedded, but certainly now is embedded in everyone's mind so that if someone comes into even the smallest facility with symptoms that are suggestive of Ebola, it is almost instinctive now that you are going to ask, Have you had any recent travel, wherever that may be? If they West Africa, a big red flag goes up, and that is when you -- and that is why the CDC right now working with the State and local health authorities are trying to say that not every hospital in the United States should be able to take care intensively of an Ebola patient,

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but you should at least be able to recognize and temporarily isolate them until you get the proper transportation to a facility that can. So I think, Dr. Burgess, that we are very, very different than we were a couple of months ago.

Dr. Burgess. Yeah. I just hope we don't have short memories.

Dr. Fauci. Yeah.

Dr. Burgess. Let me just ask for the entire panel, is there any development in your agencies in the past week that you would like to highlight or note as this committee concludes?

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[12:30 p.m.]

Admiral Redd. Yes, I am actually going to answer the previous question that one thing that we have done also --

Dr. Burgess. Yes.

Admiral Redd. -- to make sure that that situation that you described doesn't happen is track all of the individuals who travel from West Africa so that if a person does develop symptoms, they are in touch with the health department, with CDC, and we can route them to a place where they will get the kind of care that they need. That is not really the last week, but that is something that is getting better and better.

Dr. Burgess. And that is a 24-hour-a-day contact that they have available to them?

Admiral Redd. Yes, sir.

Dr. Burgess. Dr. Robinson?

Mr. Robinson. It may seem like a small milestone, but it is a big one for us because our field finish manufacturing network that was only set up 2 years ago, actually yesterday we awarded a task order, the first task order to actually put ZMapp into vials, and so over the next couple of weeks, the bulk product will be going from Kentucky to

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Indiana and to Nanotherapeutics and Baxter, and they will be filling it into the proper containers and making it available then to the NIH to do the first clinical studies in January. So, for us, it actually shows it is happening right now.

Dr. Burgess. Yeah, that is big news. I appreciate you sharing that with the subcommittee.

Oh, sorry, Dr. Fauci?

Dr. Fauci. Just one comment, Dr. Burgess, that I would like to make because it has come up several times in the hearing, and in fact Mr. Murphy had said that sometimes when I, he heard that when I respond to a question like this, I do it in a condescending way. It isn't so. We are very sensitive to the situation that is going on right now in Africa. And we want to do two things: no harm and help people. And that is what drives the need to do the kinds of trials that, in fact, may seem to some to be insensitive because they have a control arm, but I have to tell you from decades of experience of things that have gone wrong when you don't get the right answer, it is not because we are insensitive and it is not because we are arrogant. We really feel very strongly that we want to help people and, on the way, not hurt people, and that is very important. So I just wanted to make sure -- he isn't here, I wanted to get it on the record so that --

Dr. Burgess. I appreciate you sharing that with us, and I did recognize that you had wanted to say something, and we moved on on the

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panel, and I actually thank you for bringing that to our attention. That is a very important point.

And we on this subcommittee do appreciate your service at the NIH. It is something the country would be at a loss without.

And thank all of you for sharing with us today. I remind members they have 10 business days to submit questions for the record. I ask the witnesses to respond to the questions promptly. Members should submit their question by the close of business on Friday, December 5th.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:31 p.m., the subcommittee was adjourned.]