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RPTR ZAMORA

EDTR SECKMAN

EXAMINING H.R. 3299, STRENGTHENING PUBLIC HEALTH EMERGENCY RESPONSE ACT

THURSDAY, MAY 19, 2016

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Guthrie, Shimkus, Murphy, Burgess, Lance, Bilirakis, Ellmers, Brooks, Collins, Green, Engel, Capps, Schakowsky, Butterfield, and Pallone (ex officio).

Also Present: Representative Eshoo.

Staff Present: Rebecca Card, Assistant Press Secretary; Carly McWilliams, Professional Staff, Health; Graham Pittman, Legislative

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Clerk, Health; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Sophie Trainor, Policy Advisor, Health; Waverly Gordon, Minority Professional Staff Member; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; and Kimberlee Trzeciak, Minority Health Policy Advisor.

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Mr. Pitts. Ladies and gentlemen, if our guests will take their seats, the subcommittee will come to order. The chair will recognize himself for an opening statement.

Today's hearing will take a closer look at bipartisan legislation introduced by our Energy and Commerce Committee colleagues Representative Brooks and Eshoo, H.R. 3299.

[The bill follows:]

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Mr. Pitts. This bipartisan bill builds upon our previous work to modernize our biodefense systems, ensuring that we are well equipped to handle current and emerging biothreats.

The biothreat is not new. Pandemics have occurred throughout history. There have been four flu pandemics in the United States since 1918, each with different characteristics such as the H1N1 flu most recently in 2010. Even more worrisome is the threat of biological weapons or infectious diseases employed as weapons of terror, such as the use of salmonella in Oregon in 1984 by the Rajneeshee cult or the anthrax scare in 2001.

Science has made significant advances in genomics and genetics and biotechnology that hold tremendous promise for those affected by illness and disease. However, that same technology could theoretically be used to biologically engineer superbugs that are more virulent, more lethal, more difficult to treat than their naturally occurring counterparts.

Imagine a weaponized and bioengineered version of the Ebola virus or polio or smallpox, and the devastating effect that would have on an American city.

Since the terror attacks on September 11, 2001, Congress took steps to build our Nation's health infrastructure and foster a development of medical countermeasures, MCM, in the event of a future chemical, biological, radioactive, or nuclear, CBRN, attack.

In 2004, Congress enacted the Project BioShield Act, and later, in 2006, enacted the Pandemic and All Hazards Preparedness Act, PAHPA,

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which was authorized through 2011. In addition to establishing a strategic plan to direct research, development, procurement of MCMs, PAHPA also established the Biodefense Advanced Research and Development Authority, BARDA, within the Department of Health and Human Services.

BARDA was charged with coordinating and accelerating the development of MCMs. BARDA was created from the understanding that most MCMs needed by the Nation did not yet exist, and their development is a risky, expensive, and lengthy process. There is little to no demand in the private market for vaccines and therapeutics that protect against bioterror agents.

BARDA bridges the funding gap between early stage research and the ultimate procurement of products for the National Stockpile under Project BioShield. By partnering with private industry, using money from the Biodefense Advanced Research and Development Fund, BARDA, can reduce the development risk entailed in MCM research, thereby helping to mitigate the disincentives associated with countermeasure development and ultimately improving our national readiness with regard to a CBRN attack.

The bill before us today reforms our Nation's medical countermeasure acquisition process, incentivizes research to combat the next generation of deadly diseases, and increases accountability of preparedness spending. Such improvements will go a long way toward helping our preparedness for future public health emergencies, such as Ebola, by creating new incentives for developing necessary medicines

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and vaccines and streamlining the contracting process for medical countermeasures.

Incentives are necessary to attract private investment in product development, and so too must the contracting processes be efficient. We must get this right. The stakes are too high, the cost of failure too dire. And I look forward to our discussion today about how to best protect our country from biological threats.

Mrs. Brooks, do you seek time?

[The prepared statement of Mr. Pitts follows:]

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Mrs. Brooks. Yes, Mr. Chairman.

Mr. Pitts. The chair will recognize Mrs. Brooks for her time.

Mrs. Brooks. Thank you, Mr. Chairman.

I want to thank you and the leadership of the Energy and Commerce Committee so much for holding this important hearing today on our bill. Congresswoman Eshoo and I and our staffs have worked very hard over the course of this Congress to craft this piece of legislation that now enjoys significant support from both sides of the aisle. And I commend the chairman for understanding the urgency of this matter.

Last Congress, I served as chairman of the Homeland Security Committee's Subcommittee on Emergency Preparedness and Response, where I was amazed to learn of truly what I thought was the dire straits our biodefense capabilities are in as a result of more than a decade of neglect. I wish I could sit here today and tell you that I think things have improved dramatically over the last couple of years. And I appreciate from your written testimony that some of you believe they have.

Mr. Pitts. If you will suspend, I will recognize you for the chairman when he comes in. You will have more time.

Mrs. Brooks. Oh, I am sorry.

Mr. Pitts. The chair now will recognize the ranking member of the subcommittee 5 minutes for an opening statement.

Mr. Green. Thank you, Mr. Chairman, and to our witnesses for joining us this morning.

The Federal Government has undertaken many initiatives,

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especially since the anthrax attacks of 2001, to fortify our biodefense capabilities to address the threat of a biological outbreak or attack. With stockpiling medical countermeasures, MCMs, to build public health capacity, we are better prepared today than we were a decade ago.

But the fact is we still are dramatically underprepared to respond to biological event of disaster proportions. The current Zika virus epidemic underscores our need for a robust pipeline of vaccines and treatments effective against current and emerging threats. Over the last decade, the amount of cooperation between government and the private sector has improved and our level of preparedness has increased, but we must do more in order to meet the new challenges we face.

Currently, the Federal Government's biodefense initiatives span across a number of agencies and vary in scope and approach. Department of Homeland Security, Department of Health and Human Services, and Department of Defense each play a role.

For example, HHS operates the Biomedical Research and Development Authority, or BARDA, which was created to advance capability to develop, manufacture, and distribute medical countermeasures, like vaccines, during public health emergencies. BARDA is housed within the Assistant Secretary for Preparedness, or ASPR, the agency responsible for leading prevention, preparations, and response to the adverse health effects of public health emergency disasters.

H.R. 3299, Strengthening the Public Health Emergency Response Act, offers a range of ideas to move our biodefense and medical

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countermeasures development and procurement capacities forward. I want to thank the bill's sponsors for their leadership. Medical countermeasures are essential to our Nation's health and security. There is a clear and vital role for the Federal Government to play in order to contribute to a greater public health security and ensure preparedness against biological threats.

We need meaningful countermeasures, research incentives, transparency, and predictability, and flexible contracting mechanism in order to shore up our ability to respond to biological threats and infectious disease outbreaks. Without strong commitment from the Federal Government, public-private partnerships, predictable processes and incentives, this market arguably could not exist.

The government is the only market for most of the medical countermeasures. Unlike other drugs and vaccines, these products are not sold or distributed within the healthcare system. To incentivize companies to develop and produce these critical products, Congress created the Project BioShield Special Reserve Fund in 2004. The Special Reserve Fund was a market for medical countermeasures and was originally funded through the advanced appropriations at $5.6 billion over 10 years to procure successful product candidates.

The availability and certainty this 10-year fund offered had a positive impact on the government's ability to attract innovative companies into this space. Twelve MCMs against several national security threats were delivered to the National Stockpile under this program. Unfortunately, in fiscal year 2014, we shifted to annual

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appropriations for the Special Reserve Fund, which created an uncertainty where there was once confidence that there would be a markup for urgently needed new vaccines and treatments.

The market guarantee for successful MCM candidates is much weaker, and funding has dropped significantly. While Congress has many levers and options to incentivize development, many of these simply nibble around the edges and fall short of making up with the lack of long-term sustained funding. This Congress, I cofounded the Public Health Caucus to evaluate the conversation around public health and emergency preparedness.

We need to break the cycle of lurching from crisis to crisis, outbreak to outbreak, and invest in public health infrastructure and medical product development that protects us against current future threats. H.R. 3299 puts forth a range of reforms to improve MCM development and procurement response to emerging infectious diseases and hospital preparedness.

While I have some concerns about the aspect of the legislation, I believe we can find common ground and strike the right balance to protect the health and welfare of our Nation. And I want to thank the stakeholders for their willingness to work with us and look forward to learning more about their proposals in today's hearing.

And I want to thank, again, our panel and the chairman for calling this. I think sometimes we are not topical, but with Zika and 2 years ago Ebola and no telling what is coming next, this is a very important hearing.

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And, Mr. Chairman, I will yield back my time.

[The prepared statement of Mr. Green follows:]

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Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentlelady, Mrs. Brooks, for 5 minutes for opening statement.

Mrs. Brooks. Thank you, Mr. Chairman.

I want to thank you so very much and the leadership of Energy and Commerce for holding this hearing today.

This legislation now enjoys significant bipartisan support from both sides of the aisle, including 21 members of Energy and Commerce, and I commend the chairman for understanding the urgency of this matter.

Imagine for a second if the weapons used in San Bernardino, Paris, or Brussels were not guns and bombs, but instead aerosolized smallpox. And this isn't farfetched. In fact, I learned last week at a simulation at the McCain Institute in Washington that this easily weaponized, highly contagious disease could result in the death of upwards of 1 million people if dispersed in Madison Square Garden alone.

That number is not just for New York City. But in reality, those expose individuals would have returned home infecting every person with whom they came into contact along the way. And for a disease with a 30-percent kill rate, responsible for the deaths of 300 million people in the 20th century alone, the fallout would be global and catastrophic.

So I have been working with my good friend from California, Congresswoman Eshoo, one of the original architects of Project BioShield, to develop a set of policy changes that could make a difference in the next outbreak or, God forbid, a terrorist attack. H.R. 3299 was developed in collaboration with leading experts in

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biodefense, academia, first responders, and the private sector.

Among other things, this bill would reform contracting procedures at BARDA to ensure faster development of critical medical countermeasures and create a limited priority review voucher for diseases on DHS' material threat list. Returning this negotiating authority to BARDA will alleviate the bureaucratic red tape, make an immediate impact on the development of vaccines and treatments, and the new PRV program will spur development in an effective vaccine to stockpile against threats like Ebola, anthrax, or smallpox, which often take more than a decade and cost hundreds of millions of dollars.

So when you think about how we can improve our system, we could have possibly saved lives if we had an Ebola vaccine -- thousands of lives -- had it been deployed to West Africa. Or the Zika vaccine could have possibly already last spring have been in process and saved pregnant women in Brazil. The impact can be immeasurable if we make improvements and acknowledge that the system can be improved.

And so these are commonsense reforms. But they are not just coming from Congress. This Blue Ribbon Study Panel, the National Blueprint for Biodefense, listed 33 recommendations to improve our biodefense. It was authored by experts, some of whom have testified before our committee. It includes leaders such as former Senators Tom Daschle and Joe Lieberman; former Governor Ridge; Donna Shalala, the former HHS Secretary under President Clinton.

Now, a similar version of our bill has been authored by Senators Burr and Casey, and it has already passed out of the Senate Health

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Committee by a wide bipartisan margin. Preparedness is not a partisan issue. It has never been, and it shouldn't be treated as such again. And so I assure my colleagues that any concerns we might have with this legislation can be addressed in a bipartisan manner because it is our duty to really support and protect the American people. I think that is Federal Government's top priority and must be our first priority.

I look forward to hearing from our witnesses, working with my colleagues to pass H.R. 3299.

And at this point, I would yield the remainder of my time to Dr. Burgess.

[The prepared statement of Mrs. Brooks follows:]

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Mr. Burgess. I thank you for yielding.

I thank the chairman for holding this hearing.

And recognizing the topic of this hearing is strengthening public health response, I hope we will spend some time visiting the recent past and expanding upon whether or not we have learned any lessons from what has happened to us in the past few years.

Almost in a twist of cruel irony, President Obama went to the CDC in Georgia and gave a talk that Ebola has not come -- this was in September of 2014. He made the statement that Ebola has not come to this country, but if it does, we will be ready. Well, less than 2 weeks later, Ebola did come to our country. It came at the back door of a hospital in the middle of the night, wasn't recognized, the patient was sent home, eventually came back, eventually died, infected two other people in the hospital. So the second part of his statement was not operative. We were not ready.

And then I saw, with this problem literally in my backyard for the section several months, just how that not being ready, how that was manifest. We didn't have the type of direction for people. And the first responders in our emergency rooms, they didn't have the type of protective equipment. What was posted on the CDC Web site was woefully inadequate, as we unfortunately learned later, when two nurses were infected at the hospital.

When people were looking for the type of protective clothing that they would need, if someone showed up in the middle of the night of their emergency room, how can they get an additional moon suit or two?

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Do they call a hospital across town? Are they going to be willing to give up their moon suit because they could have a patient coming in within the hour with the same set of symptoms?

I hope we have explored these situations. I hope we have learned from them. One of, I think, the biggest weaknesses from 2 years ago was the lack of a single repository, a single place that a hospital administrator or manager or doctor could call to be able to access the equipment from the National Stockpile.

So, Mr. Chairman, thank you for calling the hearing. I look forward to the testimony of our witnesses, and I think this is a timely topic. I yield back.

[The prepared statement of Mr. Burgess follows:]

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Mr. Pitts. The chair thanks the gentleman.

I now recognize the ranking member of the full committee, Mr. Pallone, 5 minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman.

Since the attacks of September 11, Congress has worked in a bipartisan manner to increase our efforts to combat and respond to biological threats. However, experts have repeatedly warned that our ability to respond to biological threats must be improved.

Earlier this year, the Subcommittee on Oversight and Investigations heard from another member of the Blue Ribbon Panel on Biodefense and other experts about the U.S.' biodefense preparedness. According to this report, the Unites States, quote, "does not afford the biological threat the same level of attention as it does other threats," unquote. The report notes that we lack a centralized leader for biodefense, a comprehensive national strategic plan, and a dedicated budget for biodefense. And this review also offered 33 recommendations about how Congress and the administration can improve our preparedness.

H.R. 3299, the Strengthening Public Health Emergency Response Act, includes a number of provisions that would make progress in improving our readiness. While I support the intent of this legislation, I do have some concerns that I am interested in discussing with our panel today.

One area is related to the hospital preparedness program. This legislation would limit the amount of funding that the Assistant

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Secretary for Preparedness and Response can use to operate this program to 3 percent of the program's total funding. And I am concerned that this limitation, while well-intended, could limit the ability of ASPR to effectively oversee and evaluate the hospital preparedness program. And this limitation also would eliminate funding for other efforts that support our healthcare preparedness, response, and recovery ecosystem. So this is one thing we need to look at.

I am also concerned about the delegation of contract authority to the Biomedical Advanced Research and Development Authority, or BARDA. Like other HHS divisions, ASPR operates the contracting office for all divisions and programs under its authority. This structure ensures that Federal investments are made through a fair and open process that is free of any conflicts. Removing ASPR oversight could lead to some influence on the contracting process by the BARDA Director, another program officer and outside source.

Then, finally, I want to express some concern about further expanding the Tropical Disease Priority Review Voucher Program. This program, created in 2007, was intended to incentivize research and development of drugs to treat tropical diseases that disproportionately affect poor and marginalized populations. Once a qualifying drug is approved, the sponsor receives a priority review voucher that entitles the sponsor to a second 6-month review of any other human drug application, and the sponsor is also able to sell this voucher.

Recently, a priority review voucher sold for $350 million.

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Since creation of the Tropical Disease PRV Program, three PRVs have been awarded, and there has been a significant interest from industry and others in expanding the program as a way to encourage development of medical countermeasures.

While I believe we should explore additional ways to incentivize medical countermeasure development, I do not believe expanding the Tropical Disease PRV Program is necessarily the answer. Not only could expansion decrease the value of a PRV and the incentive to develop drugs under such programs, but it also increases the burden on FDA to expedite review of additional applications that may not otherwise qualify for expedited review.

I am concerned that expansion would only exacerbate known flaws in the current program. For example, current law requires FDA to award vouchers to sponsors even if a drug was previously approved in other countries. Additionally, there is no requirement that a sponsor market a product approved under the program; therefore, there is no guarantee that these drugs are actually helping.

So I look forward to hearing from our government witnesses on these issues. And as the committee moves forward, I hope there will be an opportunity for members to hear from additional stakeholders.

I would like to yield the minute I have left to Mr. Butterfield. Oh, he left, okay.

Then I yield back.

[The prepared statement of Mr. Pallone follows:]

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Mr. Pitts. The chair thanks the gentleman.

As usual, all members --

Mr. Pallone. Mr. Chairman, could I ask, I had three letters I would like to, unanimous consent, to enter into the record, one from Kids v Cancer, regarding added medical countermeasures to the Tropical Disease PRV Program; a letter from David Ridley, the architect of the Tropical Disease PRV Program and his Health Affairs article regarding the impact of expanding the program; and a third from Trust for America's Health.

Mr. Pitts. And I would like to add to that one letter from the Blue Ribbon Study Panel on Defense.

So, without objection, these are put into the record.

[The information follows:]

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Mr. Pitts. As usual, all members' opening statements will be made a part of the record. And we will now introduce the panel. We have one panel today, and I will introduce them in the order of their presentation.

First, we have Dr. Richard Hatchett, Acting Director, Biomedical Advanced Research and Development Authority, BARDA, and Acting Deputy Assistant Secretary in the Office of the Assistant Secretary for Preparedness and Response, ASPR, U.S. Department of Health and Human Services. Secondly, we have Mr. Michael Mair, Director of Strategic Operations, Office of Counterterrorism and Emerging Threats in the Food and Drug Administration; finally, Colonel Russ Coleman, Ph.D., Joint Project Manager, Medical Countermeasures Systems, Department of Defense.

Thank you for coming today. Your written testimony will be made part of the record. You will each have 5 minutes to summarize your written testimony.

So, Dr. Hatchett, you are recognized for 5 minutes for your summary.

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STATEMENTS OF RICHARD HATCHETT, M.D., ACTING DIRECTOR, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA), ACTING DEPUTY ASSISTANT SECRETARY IN THE OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (ASPR), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; MICHAEL MAIR, M.P.H., DIRECTOR OF STRATEGIC OPERATIONS, OFFICE OF COUNTERTERRORISM AND EMERGING THREATS, FOOD AND DRUG ADMINISTRATION; AND COLONEL RUSS COLEMAN, PH.D., JOINT PROJECT MANAGER, MEDICAL COUNTERMEASURES SYSTEMS, DEPARTMENT OF DEFENSE

STATEMENT OF RICHARD HATCHETT, M.D.

Dr. Hatchett. Chairman Pitts, Ranking Member Green, Mrs. Brooks, Ms. Eshoo, distinguished members of the House Energy and Commerce Committee, thank you for the opportunity to testify today regarding biosecurity issues and H.R. 3299, the Strengthening Public Health Emergency Response Act.

I am Dr. Richard Hatchett, the Acting Director of BARDA, and I will focus on steps taken by ASPR to strengthen our Nation's health security and the contributions of my own office toward that end.

We have made substantial progress in the past 10 years to advance the state of our national biodefense. Thanks to the support of this committee and others in Congress, we have established ASPR and BARDA and made critical investments in biodefense and our healthcare system. However, as highlighted by recent challenges, such as Ebola and Zika,

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there remain gaps in our preparedness.

Where the civilian public health and medical response to such events is concerned, the ASPR is charged by statute to play a strong leadership role. The ASPR serves as a principal adviser to the Secretary of HHS on all matters related to Federal medical preparedness and response for public health emergencies.

The ASPR is the author and custodian of the National Health Security Strategy, which focuses on protecting public health during an emergency. The ASPR chairs the Public Health Emergency Medical Countermeasures Enterprise, or PHEMCE, which coordinates medical countermeasure development efforts across the interagency. And the ASPR oversees the Hospital Preparedness Program, or HPP, which enhances medical preparedness and resiliency at the community level through its support of healthcare coalitions, which incentivize diverse and often competitive healthcare organizations to work together.

The health of communities is deeply intertwined with the abilities of its institutions to provide care to all populations. And investments in HPP are critical to limiting the cascade of negative health effects caused by disasters. The PHEMCE promotes the development and acquisition of medical countermeasures for chemical, biological, radiological, and nuclear threats, pandemic influenza, and emerging infectious diseases. And it has achieved a record of success that is now being studied as a model for global preparedness.

The strong and direct incentives we have put in place to support the development of medical countermeasures work. The PHEMCE has

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achieved technical success. BARDA has achieved technical success. Twenty three products that BARDA has supported have received FDA approval, licensure, or clearance. And the pace of success is accelerating. Fourteen of these approvals have occurred since 2011, and five have occurred in the last 14 months.

Seventeen products, ranging from anthrax antitoxins to an array of products for the management of thermal burns, have been procured for the Strategic National Stockpile under Project BioShield, with another seven anticipated between now and the end of fiscal year 2018. Over the last decade, we have honed a model of public-private partnership that works. It depends on combining push-and-pull incentives in the form of nondiluted funding and guaranteed market commitments with access to subject-matter expertise and product development services. We thank you for your continued support and sustained commitment to these programs.

To support BARDA's activities, ASPR has established a separate Office of Acquisitions, Management, Contracts, and Grants, or AMCG. AMCG is an award-winning and innovative contracting office that has led the Department in meeting contracting timelines, and its independent line of reporting mitigates potential conflicts of interest and ensures the highest standards of program integrity.

AMCG can work fast. While the departmental benchmark for contract actions is 180 days, 70 percent of our Ebola contract actions were awarded within 60 days. And the median time for recent Project BioShield and other major acquisition awards was 90 days from the

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publication of the RFP. And AMCG is fair. Last year, over 95 percent of ASPR's contract actions were competed, ensuring a level playing field for businesses capable of meeting HHS requirements. Fifty-one percent of eligible contract dollars were awarded to small businesses.

These investments in preparedness have already paid dividends. Because of the workforce in capabilities ASPR has developed over the last 9 years, we and our Nation's communities are much better prepared to respond quickly to disasters and emerging threats.

Thank you again for the invitation to speak with you, and I look forward to addressing your questions.

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[The prepared statement of Dr. Hatchett follows:]

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Mr. Pitts. The chair thanks the gentleman.

I will recognize Mr. Mair 5 minutes for your summary.

STATEMENT OF MICHAEL MAIR, M.P.H.

Mr. Mair. Good morning, Chairman Pitts, Ranking Member Green, and members of the subcommittee. Thank you for the opportunity to discuss FDA's perspective on H.R. 3299, the Strengthening Public Health Emergency Response Act, which contains provisions intended to help improve preparedness for a response to chemical, biological, radiological, and nuclear, or CBRN, threats.

FDA plays a critical role in protecting the United States from deliberate CBRN threats and naturally incurring infectious diseases, such as Zika virus and pandemic influenza. FDA is responsible for ensuring that medical countermeasures, including drugs, vaccines, and diagnostic tests, to counter these threats are safe and effective.

We work closely with our interagency partners, including our partners seated here with me today, as well as with product developers to facilitate to the development and availability of medical countermeasures. This collaboration has been extremely successful. For example, since 2000, FDA has approved 89 medical countermeasures for CBRN threats and pandemic influenza, as well as 17 supplemental changes to already approved applications and 71 modifications to diagnostic devices. This success is in part due to the continuing support provided by Congress in establishing the programs and

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authorities necessary as well as providing the funding needed to create and sustain a robust Medical Countermeasures Enterprise.

As you know, H.R. 3299 contains a provision intended to help incentivize medical countermeasure development by enabling product developers to receive a priority review voucher, or PRV, under FDA's Tropical Disease PRV Program provided certain criteria are met. The PRV may be used by the product developer who receives it or sold to another product developer who may then use it to obtain priority review for a product application that otherwise would not receive priority review.

When a marketing application receives a priority review designation, FDA's goal is to take action on that application within 6 months, as compared to 10 months under standard review. Thus, the PRV enables the product developer to potentially bring a product to market sooner than it would under standard review time, which is valuable to product developers.

While FDA fully supports the intent in H.R. 3299 to further incentivize the medical countermeasure development, we do not believe that adding CBRN threats to the Tropical Disease PRV Program is likely to achieve that goal. Only three PRVs have been awarded to date under the Tropical Disease PRV Program since its inception in 2007, and these were for products that had been in development prior to the creation of the PRV program. Thus, it remains unclear at this time how effective this program is in spurring product development, particularly for new product development.

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And even if PRV has ultimately proved successful in incentivizing product development, expanding the Tropical Disease PRV Program to CBRN threats has the potential to increase the number of PRVs that are issued over time, which could negatively affect the sales value of PRVs and thus the ability of the PRV program to do what it is intended to do: incentivize product development.

As Dr. Hatchett noted, the U.S. Government already provides significant incentives to help facilitate medical countermeasure development, including funding for research and development, clinical trial costs, and procurement contracts, and extensive technical assistance throughout the development process. These incentives have been highly successful in facilitating the development of medical countermeasures required for emergency preparedness and response. Therefore, it is unclear that extending PRVs to CBRN threats is sufficient or even necessary to incentivize additional medical countermeasure development.

FDA is also very concerned that adding CBRN threats to the Tropical Disease PRV Program will have a negative impact on FDA's ability to support product development. PRVs are redeemed for products that would not otherwise qualify for priority review, such as drugs to treat conditions for which safe and effective therapies often already exist: for example, elevated cholesterol or diabetes.

The clinical trials for these applications are typically more numerous, involving thousands more patients, and more complex than for the types of products that would normally qualify for priority review.

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Reviewing such applications within the target 6-month priority review timeframe is very challenging and requires many more person hours and a larger review team. Thus, managers and reviewers must refocus time and resources away from other important public health work.

If there are more PRVs being issued and redeemed as a result of the proposed expansion of the Tropical Disease PRV Program, FDA will have fewer resources available to review other marketing applications, including for serious diseases for which no available therapies exist.

These resource constraints will also undermine FDA's ability to conduct its portfolio of public health work from providing advice and guidance in the early stages to help facilitate product development, including for medical countermeasures, as well as to monitoring safety and approval. Given the uncertainty related to the utility of extending PRVs to CBRN threats and the potential negative unintended consequences associated with doing so, FDA believes Congress should approach the expansion of the PRV program to CBRN threats with caution.

We suggest that it would be advantageous to conduct a full assessment of U.S. Government medical countermeasure programs to determine if additional incentives are needed, and if so, bring together key experts and stakeholders to explore the most appropriate incentives to add.

Thank you, and I will be happy to answer any questions you may have.

[The prepared statement of Mr. Mair follows:]

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Mr. Pitts. The chair thanks the gentleman.

I recognize Colonel Coleman 5 minutes for your summary.

STATEMENT OF COLONEL RUSS COLEMAN, PH.D.

Colonel Coleman. Good morning. Chairman Pitts, Ranking Member Green, and distinguished members of the subcommittee, thank you for the opportunity to testify on Department of Defense efforts to partner with industry on the development of medical countermeasures that threaten our deployed military forces. I am talking about chemical, biological, radiological, and nuclear agents, CBRN.

As the DOD Joint Project Manager for Medical Countermeasures Systems, my mission is the advanced development, procurement, and sustainment of FDA-approved diagnostics, vaccines, and therapeutics needed to protect the warfighters from these deadly hazards.

I am one of five Joint Project Managers within the DOD's Joint Program Executive Office for Chemical and Biological Defense, which is the material developer for the Department of Defense Chemical and Biological Defense Program, providing full-spectrum capabilities against CBRN attacks. Today, available economic and regulatory incentives have not succeeded in encouraging the industry to partner with the Department of Defense on the development of medical countermeasures against CBRN hazards.

In general, medical countermeasures against these threats for the military would be used in rare emergency situations. And the military

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market is small. We are talking, you know, a couple hundred thousand forces, not tens of millions or hundreds of millions. This market is small so that it is unlikely to yield an acceptable return on investment for our industry partners. And industry performers, in my talks with them, have indicated that return on investment is their top priority, and there is simply little or no benefit in targeting these low-likelihood, high-impact threats.

I personally believe that incentives are needed to inspire additional innovation in this market. There are a variety of potential incentives that could be used to encourage this investment, and the Department of Defense recognizes that the development of incentives will require a careful assessment of the risks and benefits that extend well beyond just the Department of Defense.

Please recognize that we are not idle in the face of the challenges we have. My organization is taking steps to increase the Department of Defense's ability to more rapidly develop and field medical countermeasures for the Joint Forces.

We have recently announced the award of an other transaction authority consortium specific for the development of medical countermeasures in order to make it easier for nontraditional defense contractors, such as pharmaceutical industry, to partner with the Department of Defense. The OTA is a special contracting vehicle that has flexibility that is appealing to the pharmaceutical companies.

Additionally, my office is standing up the DOD Medical Countermeasures, Advanced Development, and Manufacturing Capability,

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a dedicated and enduring capability to conduct advanced development and manufacturing of products for the warfighter. This facility will make it easier and more likely that small biopharmaceutical companies, with which the DOD already engages but who lack the necessary experience with the FDA and with manufacture and production, to actually succeed at filling our DOD role.

The bottom line is that the DOD is determined to field and fully fulfill those validated warfighter requirements that will provide those urgently required capabilities against CBRN threats. I applaud the conversation now ongoing as to which incentives can best meet those requirements and generate innovation in this area.

Thank you again for the opportunity to provide my perspective. I look forward to continued congressional efforts to achieve results for the warfighter and the taxpayer.

[The prepared statement of Colonel Coleman follows:]

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Mr. Pitts. The chair thanks the gentleman.

We are voting on the floor. We still have time to begin questioning, so I will begin the questioning. I recognize myself 5 minutes for that purpose.

Colonel Coleman, the Department of Homeland Security has identified 13 material threats to U.S. national security. Would a PRV for threats on the material threat list help develop new MCMs for DOD? And why is it so important that we make sure these products are developed?

Colonel Coleman. Thank you, sir. There is a Department of Homeland Security threat list, the material threat list, and a DOD threat list. They have many commonalities. So I believe that the availability of PRVs for agents on that material threat list would be of value to the Department of Defense.

As to the second part of your question, why is this necessary for the Department of Defense? We face a myriad of threats on the battlefield. Our environment is fundamentally different from that face defending the homeland. We deploy our military forces to remote areas of the world where we have an austere environment, limited resources, difficult situations. And so the situation for the military is not the same as for the homeland.

There are a myriad of threats that we face, and we don't have capabilities against many of them. We recognize the need, and we have ongoing problems and programs. The best example I can highlight is Ebola virus in the recent outbreak that is so fresh in our minds. I

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deployed to Zaire in 1995 as part of a small team dealing with an Ebola outbreak. At that time, I was given a thermometer. This was the medical countermeasure available. Take your temperature, and we will throw you in the isolation ward.

Flash forward 20 years, and while the government has been actively involved in developing countermeasures for Ebola virus, what did we have? We did not have FDA-approved products. Yes, we had experimental compounds that all of us worked to make available to help save lives, but we had not been able to get them over the finish line. From my personal perspective, again, for the military, it is the lack of industry interest just because of the lack of return on investment.

We wish that, for our military needs, we would have a large enough guarantee that we would buy enough product to make it worthwhile. That is just not the case for the military. So alternative incentives, in my mind, could replace the return on investment. Now, I have to caveat, these are my personal perspectives and not a Department of Defense position. There is no real position from the Department of Defense on the value of priority review programs, but there is great interest in better understanding the incentives that could be made available.

Thank you, sir.

Mr. Pitts. Thank you.

Mr. Mair, you said, in 2009, in an article that you authored, quote: "Priority review vouchers are an innovative, high-impact, low-cost mechanism for encouraging the development of new medicines and vaccines for infectious diseases," end quote.

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In your testimony, you say that concern that extending the Tropical Disease PRV Program to CBRN threats may not effectively incentivize medical countermeasure development. Have you changed your position? Explain, you know, the change there.

Mr. Mair. Thank you. So back when I wrote about the value -- potential value of PRVs for CBRN threats, I initially got -- it was initially not even a program that was anything but an idea back in 2007 when I initially published on that. And at that time, PRVs were only an idea, and then since that time, Congress created the Tropical Disease PRV Program, and then we also have now a pediatric rare disease PRV program.

So both of those programs now exist, and they have a lot of products that you could get through under that. So my concern at this point is twofold: One is that to continue to increase the program will reduce the value of the vouchers. And so it is unclear that to keep growing the program is going to undermine the program. And so there is that problem and also the issue of the effect on FDA's ability to conduct its work. At the time, I didn't appreciate that because I was not in government. And it sounded at the time like it was reasonable that FDA could charge an extra user fee and they would be able to bring on extra staff to do the extra work associated with those PRV reviews. But it turns out that it doesn't work that way because we can't just staff up quickly because those fees are one time and unpredictable.

And so the effect on FDA's ability to do its other work is sort of balanced against the value of the PRV. And also, at this time, it

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is not even clear that these PRVs are really valuable to the developers who might get them, especially if we continue to grow the program and they become less valuable.

Mr. Pitts. Thank you.

I have a question for you, Dr. Hatchett, but my time is expired for now, so I will recognize the ranking member.

Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

Dr. Hatchett, thank you for joining us today. I think it is important to understand each element of H.R. 3299. I would like to focus on the provision which would give BARDA its contracting authority. When BARDA was created in 2006, Congress gave the agency sole authority to negotiate and execute medical countermeasure contracts to ensure that it would react quickly to the development of vaccines and appropriate solutions.

My understanding is that the contracting was moved from BARDA to AMCG in 2009 in order to streamline ASPR's internal process. However, I heard from stakeholders that this transition has several unintended consequences which serve to slow down the procurement process for medical countermeasures. For example, companies often respond to BARDA requests to submit proposals with a 24 to 48-hour turnaround only to have these proposals language in the AMCG's review process for multiple weeks or months.

Countermeasure and development is critical to our national security and requires a more urgent and efficient contracting process

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than traditional grants at HHS. Though I am sure AMCG is well intended, they do not appear best suited to deal with the complexities of vaccine or medical countermeasures development the way BARDA does.

Dr. Hatchett, I know you have only been on a job for a couple of months, but do you believe that we could achieve more efficiencies in the contracting process? If so, what recommendations would you have for this committee?

Dr. Hatchett. Thank you, Mr. Green. Thank you for the question.

Let me address the major part of the question first, which is whether I think that we should move the contracting activity within ASPR back into BARDA. And I actually do not think that we should do that. There were good reasons of policy, as opposed to just streamlining ASPR's contracting activity, that underlay the decision to move that contracting activity out of BARDA and to have it provide a separate line of reporting directly to the Assistant Secretary for Preparedness and Response.

Having the independent contracting authority provides checks and balances, obviously. It helps ASPR conduct its business with autonomy, without either the perception or potentially the reality of undue influence by the BARDA Director. And it allows the Assistant Secretary, which is a Senate-approved Presidential appointment, to provide direct oversight of the contracting activity within ASPR.

Mr. Green. I have got some other questions. And I understand the separation of powers and the checkpoints, but I also know that,

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if it is an emergency, you know, for the companies to submit the contract within 48 hours, why would it take months to do it if we actually had an emergency that we needed? And a good example is Zika, which we are experiencing right now.

Dr. Hatchett. So Zika is a good example. Thank you for that question. When it is an emergency, our AMCG, our contracting office can act very, very rapidly. In fact, during the Zika crisis, there was an incident that was potentially going to turn into a medical crisis where FDA issued guidance about the collection of blood in areas where ongoing Zika transmission was occurring, and it was going to require blood collection in areas with active Zika transmission to be stopped.

We learned about the impact that this was going to have on Puerto Rico, which could potentially produce a medical crisis there, on February 24, and within 6 business days, our contracting office had issued contracts to support the emergency delivery of blood to Puerto Rico. And 1 day after the contract was issued, blood supplies began to be moved to Puerto Rico. That was in Zika.

During --

Mr. Green. And I appreciate that, you know, but, again, we all have to be on our toes. Two years ago, it was Ebola, and now it is Zika. And, you know, where I come from in Texas, we have a lot of other challenges that -- but I appreciate it.

What other serious infectious disease threats is ASPR and BARDA monitoring and is concerned about the potential impact on public health? And what sustained approaches and questions and steps can be

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taken to prepare for emerging threats before they reach the level of being immediate and urgent public health concerns?

Dr. Hatchett. So we are constantly scanning to act proactively if we detect emerging threats. We are, for example, paying very close attention to the yellow fever outbreak in Angola at present and monitoring the manufacturing capacity in status of yellow fever vaccine stockpiles. We certainly are continuing to monitor Ebola. We are working very closely with the international community. There is an ongoing effort right now to prioritize known emerging pathogens in terms of the potential threat they face.

Mr. Green. Okay. Mr. Chairman, thank you. I would like to ask unanimous consent to place in the record a letter from the Doctors Without Borders.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

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Mr. Pitts. We are voting on the floor. We still have a couple of minutes left to vote. There are 11 votes, so we are going to stand in recess until the conclusion of those votes. It should be around 11:30.

So, without objection, the committee stands in recess.

[Recess.]

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RPTR KERR

EDTR HOFSTAD

[12:07 p.m.]

Mr. Pitts. All right. Thank you for your patience. The time of recess having expired, we will reconvene the hearing.

And the chair now recognizes the gentlelady from Indiana, Mrs. Brooks, for 5 minutes of questions.

Mrs. Brooks. Thank you, Mr. Chairman.

And I would ask unanimous consent to provide to the record five letters of support for a bill, H.R. 3299: one from Douglas Bryce, Joint Program Executive Officer for Chemical and Biological Defense from the Department of the Army; one from the Alliance for Biosecurity; one from the California Life Sciences Association; one from the Biotechnology Innovation Organization; and one that is categorized from a number of venture capital firms.

Mr. Pitts. Without objection, so ordered.

[The letters follow:]

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Mrs. Brooks. Thank you.

Dr. Hatchett, I realize that you have only taken over very recently as the BARDA Director, as recently as last month, but I am curious, and I would like to share with you some statements that your predecessor, Dr. Robin Robinson, told this committee under oath last year in November of 2015.

He was asked the question if he believed that additional incentives were needed to get the private sector involved in the medical countermeasures development, and he answered yes.

He also, when asked if he believed that creation of a priority review voucher limited to the material threats identified by DHS would be a useful incentive for the private sector, he answered yes to that as well.

And when asked if he believed Congress gave BARDA the unique contracting authority based on its unique national security mission, he answered originally yes.

When asked if it would be helpful to further expedite the medical countermeasures contracting process, he answered yes.

And, finally, he asked if it would be helpful, most directly, for BARDA to have direct control over its advance development and procurement contracts as it has in the past. And he indicated, whatever would be helpful, whatever we could do, yes.

And so could you please explain the agency's and the leader of the agency's dramatic shift in thinking? And I appreciate your praise of, you know, ASPR's contracting authority and so forth, but how is

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it that the leader of BARDA previously has a 180-degree different view than you do?

Dr. Hatchett. Thank you for giving me the opportunity to address that. Would you like me to address the question about incentives in the priority review voucher first, or would you like me to tackle the contracting?

Mrs. Brooks. Whichever you prefer.

Dr. Hatchett. Okay. Let me start with the incentives question.

We are very concerned about ensuring that we have appropriate incentives in place to support medical countermeasure development. As you and the members of the committee know, most of the medical countermeasures do not have viable commercial markets that can justify their existence. And in the absence of an appropriate set of incentives -- and I do think it is important that we have a set of incentives -- that development just will not take place. And it has taken us over a decade to get a set of incentives in place that have begun to show results, as I mentioned in my original testimony.

I believe, with respect to the priority review vouchers, that -- I certainly also hear from our partners in industry about their interest in seeing the priority review voucher being extended into this space. My perception is that the reason they are interested in seeing a priority review voucher extended into this space -- a priority review voucher is what we call a pull incentive. It is a prize for delivering, you know, the goods. It is not to help them perform research, but it is something that we give them when they succeed. We --

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Mrs. Brooks. But just, if I could clarify --

Dr. Hatchett. Yes, ma'am.

Mrs. Brooks. -- this involves no taxpayer dollars. Is that correct?

Dr. Hatchett. The priority review voucher does have costs. They are distributed differently. It is not a direct taxpayer-dollar-funded incentive.

But it is a pull incentive, because if a company can receive a priority review voucher, then they have this prize which they can trade on the open market, and it provides potentially a great deal of value to the company.

My perception is that the companies that have expressed support for this are expressing support for a new pull incentive because of their concern about our collective commitment to the biodefense enterprise. Without a sustained, substantial commitment to supporting medical countermeasure development, they, I believe, view the addition of a new incentive as potentially valuable.

I believe that the incentives that we have in place, if they are sustained and fully supported, are demonstrating that they can work. And that is why I differ with my predecessor about the value of a priority review voucher. I understand the interest in the priority review voucher. I am not denying that it serves as a pull incentive. But I believe there are more direct and less deleterious ways that we can achieve success.

Mrs. Brooks. But would you agree with me, though, it is certainly

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not just the private-sector companies who engage in this space. It also was endorsed in a significant way by the National Blueprint for Biodefense by the blue-ribbon panel. And so a number of experts for a long period of time believed that this would be the way forward. In fact, it is a number of their recommendations.

Dr. Hatchett. We are very interested in looking at all potential incentives that can be brought to the table.

And the one other thing that I would say is that, in the various spaces that we work in, for CBRN threats, for pan flu, for antimicrobial resistance, and now for emerging diseases, the market failures for each of those areas differ, and I believe that they will require potentially different sets of incentives to achieve success against each of those threats.

Mrs. Brooks. Thank you.

Mr. Chairman, I failed to also ask if we could submit for the record -- I know that you, I believe, in your questioning, mentioned prior articles written by Dr. Mair. And I have two articles with respect to the priority review vouchers and the value that I would like to submit for the record written, in part, by Dr. Mair.

Mr. Pitts. Without objection, so ordered.

[The articles follow:]

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Mrs. Brooks. Thank you. My time has expired. I yield back.

Mr. Pitts. The chair thanks the gentlelady.

I now recognize the vice chairman of the subcommittee, Mr. Guthrie, for 5 minutes.

Mr. Guthrie. Thank you.

Thank you all for being here and your patience. We appreciate it.

Mr. Mair, I know that you have claimed that when a priority review voucher is redeemed, FDA has a harder time reviewing other priority review applications on time. However, in its most recent PDUFA performance report to Congress, the FDA stated that it met review goals for 100 percent of the 29 priority review applications it received. And it appears, from FDA's own data, the use of priority review vouchers has not had any impact on review times for other priority applications.

If the FDA doesn't support the priority review voucher incentive, then what other kind of incentives could be appropriate for developing countermeasures? I know you are not going to endorse any or ask for any, but what are other incentives that we could look at?

Mr. Mair. Thank you for the question.

So, with respect to the effect, I think -- with respect to the effect of the vouchers, potential effect on our ability to do other reviews, I think our concern we are raising here is expanding the program. Well, there will be more vouchers out there that will eventually come in. And so this has the potential to affect our ability to do more of our other work down the road, especially if we continue

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to expand the program.

So while, you know, one or two might by doable, if we end up getting, you know, 5, 10, 15 vouchers out there, it, you know, has the potential to grow to a point where it is --

Mr. Guthrie. Are there other incentives that might be workable if we need priorities to move forward?

Mr. Mair. You know, it is a difficult question and something we should look at, but there are -- you know, it is a question of, you know, the incentives we currently have, can we treat them, can we hone them in some way, can we improve what is currently available, or can we add new incentives to the mix, and what is most valuable, and what can get us there in the best possible way with the most value to the taxpayer in terms of getting us there most efficiently. So it --

Mr. Guthrie. Okay. Thanks. I am going to try to get through a couple more questions. I appreciate that. Thanks a lot. I wasn't cutting you off to be rude, just to get to a couple more questions in my 5 minutes.

Colonel Coleman, do you believe the Department of Defense has the requisite number of medical countermeasures developed, licensed, and available to protect our warfighters from biological agents? And, in your opinion, should Congress be doing more to encourage the development of medical countermeasures against these threats, like creating priority review vouchers for the medical countermeasures?

Colonel Coleman. Yes, sir. Thank you for that question.

So I can unequivocally say that we don't have the full array of

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medical countermeasures needed to combat weapons of mass destruction. Ergo, we have a robust program with funds provided by Congress for this express purpose. So, clearly, the needs continue, and we are a long way from where we ultimately need to be.

In terms of any Department of Defense position, there is no position, as I stated earlier -- I mean, there is a clear belief that we need an array of incentives. Personal opinion, which I think you asked, regarding priority review vouchers, I believe they could potentially be of great value.

I will refer back to the Ebola virus outbreak. Post-outbreak, I have engaged with conversations with many of the pharmaceutical companies that chose to engage at the time of the outbreak, and their interest is waning. And some of the companies have indicated that, when they choose to stay in, it is really for the priority review voucher, which was added to that neglected tropical disease threat list. So I am getting the feedback from commercial enterprises that they see the value to this.

Mr. Guthrie. Okay. Thank you.

And, Dr. Hatchett, some claim that it is important that BARDA does not have contracting authority because of potential conflicts of interest or undue influence of the BARDA Director. Why was your contracting authority taken away? And did the BARDA office lack program integrity?

Dr. Hatchett. Thank you for asking about the contracting authority again because I didn't get to answer Mrs. Brooks' question --

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Mr. Guthrie. Okay.

Dr. Hatchett. -- and would like to address her question as well.

The contracting authority was removed from BARDA, I believe, in 2009, which was prior to -- I joined BARDA in 2011.

Mr. Guthrie. Yeah. There was no implication on you in there.

Dr. Hatchett. Yeah. And I believe the concern was legitimately that contracting is such an important activity, it manages the taxpayers' dollar, that it was extremely important that it be independent and that it represent the business function of government independently in terms of negotiations with companies.

Our contracting office is right down the hall from my office. The head of our contracting authority, retired Brigadier General Jeff Scarborough, is -- you know, his office is less than 100 yards from mine. We talk every single day. Our staff interact with the contracting officer staff every single day. So, you know, there are no barriers to our working together. We work together on all contracting actions.

And in point of fact, to answer Ms. Brooks' question about why I have a different opinion than my predecessor, I have looked at the data. I have looked at the data as to the timelines for individual contracting actions as well as aggregate timelines. And it is quite impressive that we are well below Federal and departmental benchmarks in terms of our performance. There are outliers, some that are large outliers that result in, you know, the average times being actually being lower than the median times. That happens.

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But, overall, I think our contracting office is providing a service to the American citizen by ensuring the integrity of our procurement process. And I am very comfortable with the system as it currently exists. I just have a different opinion than my predecessor.

Mr. Guthrie. Thank you, Mr. Chairman. My time has expired, so I yield back.

Mr. Pitts. The chair thanks the gentleman.

Without objection, we have a member of the Energy and Commerce Committee, not a member of the subcommittee, here, one of prime sponsors of legislation. I would like to yield to Ms. Eshoo 5 minutes for questioning.

Ms. Eshoo. Thank you very much, Mr. Chairman, for your legislative courtesy.

And I would like to thank the witnesses for their testimony today.

I am very proud of the legislation that former Congressman Mike Rogers and myself shaped and shepherded to create the law that led to BARDA. We are both members of the Energy and Commerce Committee, but, very importantly, both members of the House Intelligence Committee. And we viewed this issue in many ways as the tip of the spear, that our national security is a portfolio that contains many items that must be addressed.

And so it is a pleasure to work with Congresswoman Brooks to update BARDA, but the principles, the underlying principles still remain, and that is that we be effective, that we be limber, that we be timely, that we be able to identify, that we be able to attract those who are

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actually going to produce the stockpiles for our country so that we are indeed prepared.

And I hear some back and forth here, the innards and some of the weeds and the whatever. I think we have to raise our vision and keep in front of us exactly what I just said.

So, Mr. Mair, the FDA claims that allowing biodefense medical countermeasures to qualify for a priority review voucher would dramatically increase the number of PRVs awarded. Now, DHS has identified only 13 material threats to U.S. national security, and since the creation of BARDA in 2006, 12 years ago, there have been 3 medical countermeasures.

Now, it has been stated before, it is worth stating again, that this program is privately funded. There are no taxpayer dollars in it.

How many medical countermeasures are you aware of in the pipeline that would qualify for a PRV under this bill?

Mr. Mair. Thank you for the question. I might defer that to Richard to speak to --

Ms. Eshoo. Yeah, let's go quickly, because I only have 5 minutes.

Mr. Mair. Sorry -- to Richard, what is in the BARDA pipeline.

Ms. Eshoo. How many countermeasures are you aware of in the pipeline that would qualify?

Dr. Hatchett. Ma'am, I don't have a specific number available to me. I would be happy to provide that information --

Ms. Eshoo. That would be great.

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Dr. Hatchett. -- to you and will do so.

Ms. Eshoo. And would you please provide the committee with a list of those medical countermeasures, the candidates that you believe would qualify? All right?

Dr. Hatchett. Uh-huh.

Ms. Eshoo. Dr. Hatchett, how long does your average vaccine procurement take from solicitation to award?

Dr. Hatchett. The most recent numbers that I have looked at are actually aggregate numbers of major acquisition programs. And so those include Project Bioshield procurement actions, the most recent four procurement actions, as well as three additional major acquisition --

Ms. Eshoo. Yeah, I just want to know how long does your average vaccine procurement take from solicitation to award.

Dr. Hatchett. Sure.

Ms. Eshoo. Because timeliness is of the essence in all of this. If we can't be timely -- identify, target, be timely, bring it up, have these measures in place, then this is just a piece of paper with good ideas on it.

Dr. Hatchett. So the four actions that I have data for immediately available, three of them took 90 days from solicitation to award.

Ms. Eshoo. I am asking about vaccine procurement.

Dr. Hatchett. Okay. I will have to get back to you with definitive data.

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Ms. Eshoo. Okay. I would appreciate that.

Dr. Hatchett. Okay.

Ms. Eshoo. I really don't get your reason, your thinking, and what you have testified today, Dr. Hatchett, about contracting authority under BARDA. It is the way the legislation was written originally. The Commission -- I mean, if there was ever a bipartisan commission of some of the most highly regarded individuals in public service -- they don't agree with you.

How did you arrive at your thinking? I mean, does it make it faster? More effective? What is it that you don't like about it?

Dr. Hatchett. First, in terms of how the Department of Health and Human Services handles contracting throughout the operating divisions --

Ms. Eshoo. No, I am asking you. I am asking you.

Dr. Hatchett. So I am trying to address your question, ma'am.

The contracting activity at NIH, at FDA, at CDC report directly to the director of those agencies and provide services to the components of those agencies. The contracting activity within ASPR reports directly to the ASPR and provides --

Ms. Eshoo. I think you are talking about an organization chart. I want to know, in terms of our national security and the import of what this law is about, why do you take the position that you do?

Dr. Hatchett. I take the position that I do because I understand the complaints that have been articulated by our private-sector partners, and they have gone on to propose a solution, which is to move

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the contracting authority back into BARDA.

Their complaints relate to concerns about the length of time it takes, about their interactions with the contracting authority. I believe there are other ways to address the complaints that they have articulated that preserve the integrity of our procurement process in a way that would be more effective than moving the contracting authority back into BARDA.

Ms. Eshoo. Thank you.

Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentlelady.

Dr. Hatchett, I didn't get to ask my question of you, so I would like to do that and let the ranking member or anyone else ask a followup if they would like.

I would like to read from a letter sent to Congress by a group of venture capital investors who have experience with MCMs. And they say, quote, "We have watched the biodefense enterprise struggle to attract and sustain investment and participation from companies and financial partners. The lack of sustainable and predictable incentives for companies who have promising technologies for biodefense applications is the primary driver of this struggle. Quite simply, the decision to invest in the biodefense sector is infinitely more risky than any other portion of the biotech sector," end quote.

So, Dr. Hatchett, I would like -- and I will enter into the record this letter, without objection.

Mr. Green. No objection.

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Mr. Pitts. With no objection, so ordered.

[The letter follows:]

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Mr. Pitts. Multiple developers have indicated that investors actually devalue the biodefense work they do with the U.S. Government because it is so risky and unpredictable. So my question is, if this is the case, why would anyone oppose this limited incentive for MCMs? What are your thoughts on this issue?

Dr. Hatchett. Well, thank you, Mr. Chairman, for the question.

I think you are actually making the same point that I was making earlier, which is that, in the absence of predictable and sustained incentives, it does become an extremely risky business to be in because of the absence of the commercial markets for the products at the end of the day.

I believe if the administration, whatever that flavor is, and Congress agree to provide the sustained incentives and strong support, that we have demonstrated that the system can work technically. We can bring countermeasures forward; we can address the technical challenges.

In terms of it being a risky and unpredictable business to be in, in 2010 we undertook an interagency review of the entire medical countermeasures enterprise specifically to address areas of risk that the government had some control over that could reduce that risk and make the government better partners with our private-sector partners.

And I think the results of the last 6 years since that review was performed have demonstrated an acceleration in the delivery of countermeasures. And so many of the steps that we have undertaken have addressed the different risks -- the financial risk, the technical

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risk, the regulatory risk, the risk of working with government as a partner because of the way the political winds blow.

We are extremely mindful of the risks that our partners face. We are working to address those risks, reduce those risks. And we certainly thank you for the support that you have provided so far. We ask for continued strong support for this effort because, without that support, the enterprise is jeopardized.

Mr. Pitts. Thank you.

The Ebola and Zika outbreaks have been lessons in the seriousness of the challenges we face in this space, and H.R. 3299 was written to increase the efficiency of this program administratively and incentivize the product development. And I think you agree every minute is critical. It is important that we continue to work in a bipartisan manner to improve our emergency preparedness, incentivize medical countermeasures development.

I will yield to the ranking member for any closing questions or thoughts.

Mr. Green. Thank you, Mr. Chairman.

I would like to ask unanimous consent to place an article from Health Affairs --

Mr. Pitts. Without objection --

Mr. Green. -- into the record.

Mr. Pitts. -- so ordered.

Mr. Green. Thank you.

[The article follows:]

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Mr. Pitts. All right. We will have followup questions. We have been interrupted. We apologize for that. Thank you for your patience. But members do have followup questions, and other members have written questions. We will submit those to you in writing and ask that you would please respond.

And I would remind members that they have 10 business days to submit questions for the record. Members should submit their questions by the close of business on Thursday, June the 2nd.

Very, very important issue, very important hearing. Thank you. We look forward to continuing to work with you on this issue.

Without objection, the hearing is adjourned.

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