

U.S. BIODEFENSE, PREPAREDNESS,
AND IMPLICATIONS OF
ANTIMICROBIAL RESISTANCE
FOR NATIONAL SECURITY

HEARING

BEFORE THE
SUBCOMMITTEE ON NATIONAL SECURITY
OF THE
COMMITTEE ON OVERSIGHT
AND REFORM
HOUSE OF REPRESENTATIVES
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U.S. BIODEFENSE, PREPAREDNESS, AND IMPLICATIONS OF ANTIMICROBIAL RESISTANCE FOR NATIONAL SECURITY

HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON NATIONAL SECURITY
COMMITTEE ON OVERSIGHT AND REFORM
Washington, D.C.

The subcommittee met, pursuant to notice, at 4:11 p.m., in room 2247, Rayburn House Office Building, Hon. Stephen Lynch presiding. Present: Representatives Lynch, Hice, and Welch.

Mr. LYNCH. Good afternoon. This subcommittee will come to order, and without objection the chair is authorized to declare a recess of the committee at any time.

This hearing is entitled, "U.S. Biodefense, Preparedness, and Implications of Antimicrobial Resistance for National Security." And I want to apologize, first of all, to my witnesses, our witnesses, and to our guests. As you know, as I explained earlier, to most of our guests, there is rule in the house that a subcommittee hearing such as ours cannot convene while there is a full committee hearing ongoing, and so that is where my colleague, Mr. Hice, was. There is also a rule that a subcommittee cannot begin unless one Democrat and one Republican are present to constitute a quorum. So I have to say I have never been so happy to see a Republican in my life, so we will begin.

Today's hearing will examine whether the United States is prepared to respond to various biological threats to our national security. These include natural pandemic outbreaks such as influenza, Ebola, or diseases yet unknown, as well as biological attacks which are perpetrated by foreign adversaries, terrorist organizations, and other non-State actors. We will also focus on the growing threat of antimicrobial resistance, which, according to the Center for Disease Control and Prevention already contributes to the deaths of about 23,000 Americans each year.

In the two decades since September 11, 2001, amazing developments in biotech, including synthetic biology, gene editing, and genomic engineering have led to remarkable breakthroughs in health care, clean energy, and sustainable nutrition. However, actors with maligned intent can also exploit those same technologies to develop biological weapons or agents and deploy them across our Nation and the battlefield, with potentially devastating effect.

Director of our National Intelligence, Dan Coats, underscored this risk in his 2019 Worldwide Threat Assessment, when he stat-

ed, and I quote, “These technologies hold great promise for advances in precision medicine, agriculture, and manufacturing, but they also introduce risks, such as the potential for adversaries to develop novel biological warfare agents, threaten food security, and enhance or degrade human performance,” close quote.

A previous assessment issued by former Director of National Intelligence, James Clapper, identified gene editing as a potential weapon of mass destruction, the basic ingredients of which can be bought online today for as little as \$60.

Similarly, the nonpartisan Government Accountability Office has also highlighted the dangers posed by naturally occurring infectious disease that could easily become pandemics in view of global climate change and mass human migration. These official warnings demand our continued attention. Although we are fortunate not to have experienced a biological attack here in the United States since the anthrax attacks post September 11th, the threat remains very real. Foreign adversaries have already demonstrated an interest in developing genetic and biological weaponry. According to official reports, North Korean leader Kim Jong-un is pursuing advanced bio-weapons research and production capabilities.

Andrew Weber, the Assistant Secretary for Nuclear, Chemical, and Biological Defense Programs under President Obama recently commented that “North Korea is far more likely to use biological weapons than nuclear ones. The program is advanced, underestimated, and highly lethal.”

Terrorist organizations and other non-state actors also have started to develop and deploy biological weapons. A laptop discovered from ISIS fighters in northern Idlib, Syria, in 2014, reported contained a 19-page document with instructions on how to develop biological weapons and weaponize the bubonic plague from infected animals. It also highlighted the relatively low cost of biological weapons and their potential to inflict mass casualties.

To their credit, both Democratic and Republican administrations have taken some steps to strengthen our national biodefense. Most recently, in September 2018, the Trump administration released the National Biodefense Strategy in compliance with a congressional directive, included in the Fiscal Year 2017 National Defense Authorization Act. The President has also established a multi-agency biodefense committee to be chaired by the Secretary of Health and Human Services.

Congress has also sought to enhance our national biodefense and preparedness. Earlier this month, the House passed a bipartisan legislation that will reauthorize critical funds for bioterrorism and pandemic preparedness, including \$7.1 billion for the BioShield Special Reserve Fund for the development of biothreat medical countermeasures. The bill, which the President has signed this week, also includes \$685 million in annual grant funding to states and localities through 2023, to assist them in responding to infectious diseases, biological events, and other public health threats.

Nevertheless, there are key gaps that remain. As reported by GAO, our national biodefense framework is still, and I quote, “fragmented and lacks coordination among multiple agencies.” Moreover, GAO has identified persistent challenges facing two primary biosurveillance programs operated by the Department of Homeland

Security to detect and monitor biological threats. Both the BioWatch program and the National Biosurveillance Integration Center have been hampered by technical performance deficiencies in the absence of clearly stated mission.

Our biodefense efforts must also adapt to the emergence of new biological threats, including deadly antimicrobial-resistant diseases that render existing antibiotics, antifungal, or antiviral medications virtually useless. According to an April 2019 New York Times report, the spread of a resistant fungus known as *Candida auris* has led the CDC to designate it as a serious global health threat. The CDC has already documented nearly 700 cases of this life-threatening infection in the United States. American servicemembers in Iraq and Afghanistan have also contracted drug-resistant, superbug infections threatening overall troop readiness and morale.

Robust and continued congressional oversight will be essential to enhancing our national biodefense going forward. To this end, I look forward to discussing these and other topics with today's witnesses, and I now yield to the ranking member of this subcommittee, the gentleman from Georgia, Mr. Hice, for five minutes for an opening statement.

Mr. HICE. Thank you very much, Mr. Chairman, and I am honored to be the one Republican that you are very thrilled to see today, and the feeling is mutual toward you.

I also want to take a moment to say thank you to our witnesses for your patience today, and all who are attending. Sometimes our schedules get turned upside down, and the fact that you have exhibited great patience with us and understanding, and that means a lot, so thank you for that.

I also want to extend a very personal welcome to Dr. Dallas from the University of Georgia, a good friend and a wonderful family that you have. It is good to see you here. Dr. Dallas is recognized as a great leader on this topic as well as a phenomenal professor at the University of Georgia. And with there being about two months before football season we will just publicly say "Go Dogs," and let's get that rolling.

But we are here today to discuss how our country prepares for, responds to, and recovers from potential catastrophic biological incidents and naturally occurring pandemics. Historically, our country has faced a number of significant biological incidents. For example, shortly after 9/11, and the terrorist attacks then, envelopes containing infectious anthrax spores were deliberately mailed through the U.S. postal system. Many of you will remember that. Some 22 people were infected and five deaths occurred.

In 2009, our country faced a pandemic virus that first emerged in the U.S., resulting in a worldwide death toll of between 150,000 to 575,000, according to the CDC. In 2014, there was an unprecedented Ebola outbreak in West Africa. The outbreak resulted in more than 28,000 cases and about 11,000 deaths. Eleven individuals were treated in the U.S., one of which died.

In September 2018, President Trump's administration released a comprehensive National Biodefense Strategy, as the chairman mentioned. It built on lessons learned from the past biological incidents, like the 2001 anthrax attacks and the 2009 influenza pandemic and the 2014 Ebola outbreak. President Trump has also re-

leased a National Security Presidential Memorandum to support the National Biodefense Strategy. For instance, it established a Biodefense Steering Committee, which is chaired by the Secretary of Health and Human Services, to coordinate implementation of the strategy.

These actions demonstrate the Administration's commitment to strengthen America's defense against biological threats to health and safety.

So before us today, as I have already mentioned, each of you are experts in this field and we welcome you here to deal with the bio-defense issue. We have a Blue Ribbon Study Panel representative, Government Accountability Office, and as I mentioned, representatives from both the University of Georgia and Tufts, and we are honored to have each of you here.

So we look forward to hearing your testimony, and on this side of gaining some of your expertise on this topic. So again, we welcome you here, we thank you for being here, and with that, Mr. Chairman, I will yield back.

Mr. LYNCH. Thank you. Today we are joined by an all-star panel of witnesses, and very patient witnesses. Dr. Helen Boucher is the Director of—she is my homie, Massachusetts. She is the Director of the Tufts Center for Integrated Management of Antimicrobial Resistance at Tufts Medical Center. We also have Dr. Asha George, Executive Director of the Blue Ribbon Study Panel on Biodefense; Chris Currie, Director of Emergency Management, Disaster Recovery, and DHS Management Issues, Homeland Security and Justice Team, within the U.S. Government Accountability Office—his business cards are about this big—and Dr. Cham Dallas, a Georgia native, University Professor and Director, Institute for Disaster Management at the University of Georgia.

Mr. HICE. Go Dogs, if I failed to mention that earlier.

Mr. LYNCH. Go Dogs. On the record, without objection, Go Dogs is entered into the record.

Mr. HICE. Thank you very much. Thank you, sir.

Mr. LYNCH. All right. Now, it is the custom of the committee to ask the witnesses to rise and be sworn in. Please raise your right hand.

[Witnesses sworn.]

Mr. LYNCH. Let the record show that the witnesses answered in the affirmative.

Thank you. Please be seated.

The microphones are sensitive so please speak directly into them. Without objection, your written statements will be made part of the record, and with that I welcome Dr. Boucher. You are now recognized for five minutes to give an oral presentation of your testimony.

STATEMENT OF DR. HELEN BOUCHER, DIRECTOR, TUFTS CENTER FOR INTEGRATED MANAGEMENT OF ANTIMICROBIAL RESISTANCE, ON BEHALF OF TUFTS MEDICAL CENTER

Dr. BOUCHER. Good afternoon Chairman Lynch, Ranking Member Hice, and distinguished members of the subcommittee. On behalf of the Infectious Diseases Society of America, or IDSA, thank you for holding today's hearing and inviting me to testify.

I am an infectious disease physician at Tufts Medical Center in Boston, director of the Tufts CIMAR that was mentioned, and the treasurer of IDSA. I also have the privilege to serve on the Presidential Advisory Council for Combatting Antibiotic-Resistant Bacteria. My comments today are my own and delivered on behalf of IDSA, and do not reflect the views of the U.S. Government.

As I am a clinician, I would like to start by telling you about two patients we recently treated. The first is a young lady with a history of injection drug use, who had two prior heart valve infections related to opioid use. Over the course of two to three years, she had two separate heart valve infections, the second of which was due to methicillin-resistant *S. aureus*, or MRSA, and involved her tricuspid valve that had been previously surgically repaired. Her treatment was complicated by kidney failure due to an antibiotic called vancomycin and prolonged hospitalization. Her course was further complicated with a chest wound infection, also due to MRSA.

We saw her again when she was 22 weeks pregnant, and the MRS infection had extended from chest bone into her chest. She had to have several surgeries and received another long course of antibiotic therapy while she was pregnant. She had several more hospitalizations, including some time spent in the ICU, but ultimately delivered a healthy full-term baby. Her problems have continued, however, and she may require yet another heart valve replacement.

Sadly, hers is not an isolated case. We, and most other health care facilities in the United States care for a large number of patients with drug-resistant infections related to opioid use.

The second patient is a middle-aged lady I took care of in the hospital recently. She had undergone chemotherapy for leukemia and was in remission, so there was no cancer in her body. We were called when she developed pneumonia and a bloodstream infection due to a Gram-negative bacteria that was resistant to every drug tested by our lab. When I sat down to deliver this news to her she said, "How can this be? Surely you are going to find something to treat this."

We did succeed in doing a lot of fancy testing in the lab and getting help from the FDA and collaborating with a company to get an investigational drug called cefiderocol, and gave her a combination of antibiotics, but she ultimately died 10 days later. So this lady, in the prime of her life, who had overcome cancer, died from an antibiotic-resistant infection.

It is also important to point out that with our best efforts and help from many people around the country, including here in Washington at FDA, it took four days to get the emergency use antibiotic to her, and it sort of emphasizes how important it is for us to have effective drugs in our hospital pharmacies, ready to use when our patients need them.

These and many other experiences motivate me and my colleagues to fight for solutions to this crisis. As many as 162,000 people in the United States lose their lives every year to multidrug-resistant infections. CDC also estimates that antibiotic-resistant infections result in \$20 billion in excess health care costs annually,

due, in large part, to longer hospital stays for patients in whom these infections are not easily treated.

Antibiotic-resistant infections pose a significant threat to our national security, as was mentioned. Resistant pathogens complicate our soldiers' combat wounds, increasing the risk of limb loss and death, and compromise our military's combat readiness and effectiveness. Between 2004 and 2009, over 3,300 American soldiers in Iraq and Afghanistan became severely ill from a single resistant Gram-negative pathogen called *Acinetobacter*, which has become even more resistant to treatment over time.

Alarming, as was also mentioned, resistant pathogens are a prime candidate for weaponization. The former Soviet Union successfully weaponized multidrug-resistant strains of both plague and anthrax. Studies have concluded that the aerosolized release of a weaponized, resistant pathogen in just a single incident of bioterrorism in the Washington, DC. area would result in a death toll of over 3 million. Any mass casualty event is likely to result in severe wounds and burns, which can quickly become infected and further complicated by resistance.

Antibiotic resistance also puts our health security at risk, both in the U.S. and around the world. An outbreak of a serious resistant infection with limited or no treatment options could overwhelm health systems, harm economies, and even destabilize communities and countries.

Antibiotic resistance importantly threatens to undo decades of medical progress. Many lifesaving procedures, like cancer chemotherapy, organ and bone marrow transplants, and other complex surgeries are only possible with the support of effective and safe antibiotics.

While bacteria develop resistance in nature, the use of antibiotics places selective pressure on bacteria, leading them to develop resistance even faster. Antibiotic use in animals, agricultural settings, and the environment also contribute to resistance. We must curtail inappropriate antibiotic use to limit the development of resistance. But even appropriate antibiotic use causes resistance, so we must develop a robust, renewable pipeline of new antibiotics to address our current and future threats.

Unfortunately, our toolbox of antibiotics is shrinking. Nearly all large pharmaceutical companies have left the antibiotic development field. The small companies that remain responsible for most of the antibiotic innovation are struggling to stay in business. In April, one small company, Achaogen, filed for bankruptcy, despite having received Federal support to develop and launch an important new antibiotic. Others have recently announced massive layoffs.

There are currently 42 antibiotics in development. Of these, only 16 have the potential to treat our worst infections, the Gram-negative infections, and most drugs in clinical development do not ultimately achieve FDA approval.

Factors very unique to antibiotics make it extremely difficult for companies to earn a return on investment in antibiotic R&D. Antibiotics are taken for a limited duration of time, and new antibiotics must be used judiciously to preserve their effectiveness. Incentives are needed to make antibiotic R&D feasible for companies.

Congress and the Federal Government have taken many important steps to address antibiotic resistance and spurring antibiotic R&D, and we are very appreciative. Current efforts must be maintained and new policies are needed. The problems are complex and will require multifaceted solutions that cut across multiple congressional committees.

We encourage you to support the DISARM Act, which will soon be introduced in the House. This bill will help stabilize the antibiotic market for companies and investors by boosting Medicare reimbursement for important new antibiotics. It will also help curb resistance by requiring hospitals to implement stewardship programs and report antibiotic use and resistance data to CDC.

While reimbursement reform would be an important step forward, it alone is highly unlikely to deliver the antibiotic pipeline we need. A new incentive not linked to sales volume, to provide a predictable return on investment, is necessary. We also call for increased investments in research and public health interventions to address resistance.

Once again, please accept my deepest thanks on behalf of my colleagues at IDSA, and most of all, our patients, to the subcommittee for holding this hearing and for inviting us to participate. We look forward to continued collaboration to address the problem of antibiotic resistance.

Mr. LYNCH. Thank you.

Dr. George, you are now recognized for five minutes.

STATEMENT OF ASHA GEORGE, EXECUTIVE DIRECTOR, BLUE RIBBON STUDY PANEL ON BIODEFENSE

Ms. GEORGE. Thank you, Mr. Chairman, Ranking Member Hice, and to the congressional staff, thank you for inviting us here today to talk about these issues.

I am the Executive Director for the Blue Ribbon Study Panel on Biodefense. In addition to having a doctorate in public health and having spent 30 years in the biodefense arena, I am also a Desert Storm veteran, and I bring that up really only because I know what it feels like to be operating in an arena under the specter of biological warfare. I know what it feels like to be wearing chemical protective overgarments and wonder if they are going to protect me from a biological agent. I know what it feels like to be taking a vaccine that just the week before got emergency use authorization for me to take. And I know what it feels like to be standing on a battlefield wondering if antimicrobial-resistant anthrax or some other biological agent have been loaded into a Scud missile and are coming my way.

I mention all of this because I don't want anybody in this country, particularly in this country, geographically, to ever have to feel any of those things, and I know that you don't either.

I will just add one other point here, and that is while we haven't had any other biological attacks since the anthrax events of 2001, we still have all these white powder events. I believe it was today that the DeKalb County Courthouse had to evacuate for what seemed to be a rather significant white powder event that turned out not to be anthrax, from what I understand. But just imagine

how all those people felt. That is a highly busy courthouse. There are a lot of people in there, all affected at once.

I have submitted my longer written statement for the record, but I just want to make a few points here.

The Blue Ribbon Study Panel on Biodefense addresses the entire spectrum of biodefense, so we are looking at prevention and deterrents in terms of the State Department and the Defense Department and the intelligence community, and then we look at everything beyond that as well—preparedness, detection, response, attribution, recovery, and mitigation.

And when you hear that list you think about what that must mean in terms of the government. This is a huge governmental set of activities. All of the Federal departments, eight of our independent agencies, and one independent institution, that we know about, all contribute to biodefense. That makes jurisdiction and oversight here in the House and in the Senate, obviously, extremely difficult and challenging. But I think that it points very directly to this particular committee and the need to exert oversight from here, because you have the entire picture, and look at the entire government.

We issued a report in 2015 called the Blueprint for Biodefense. In it we have 33 recommendations and 87 action items. And we assessed the state of biodefense here in the country looking at strengths and weaknesses and vulnerabilities. And the Nation remains vulnerable to this day. In short, the Nation is not prepared for biological outbreaks, acts of bioterrorism, biological warfare, or accidental releases, with catastrophic consequences, and I think that is where the national security issue comes into play, not to say that the onesy-twosy events are not worthy of our concern, but we are talking about catastrophic events that would affect the effective functioning of our entire society.

The National Biodefense Strategy that was mentioned earlier is actually one of our recommendations from our blueprint, as was this Coordination Council, although you wanted to see both of those activities run out of the White House. When you have so many governmental agencies involved we believe you need somebody above them all to run them all.

The strategy has come out, as you said, Mr. Chairman, but the implementation plan for that strategy is still pretty thin. The Department of Health and Human Services has been charged with working on that implementation plan, but they face the challenge of trying to get information out of all the other departments and agencies to inform that plan. I hope it doesn't take as long to produce that as it did to produce the implementation plan for the National Strategy for Pandemic Influenza. President Jimmy Carter issued that requirement to the Department of Health, Education, and Welfare for the strategy and the implementation plan, yet it was only released by President George W. Bush, however many decades later, and pulled away from the Department of Health and Human Services.

Just quickly about antimicrobial resistance. The panel is very concerned about antimicrobial resistance. AMR would exacerbate all the types of threats that I mentioned earlier. Our national policy, which seems to focus quite a bit on hospitals and health care,

looks at these individuals, these patients, and then says we have to get them out of the hospital as soon as we can, because we are trying to reduce their exposure to these resistant organisms within these hospitals.

I would leave it to my colleagues to discuss how effective that actually is, but it is not a national security policy. It is not good national policy. If we were to be attacked or experience a naturally occurring disease that has become resistant, that affects a large population or populations here in the United States, we would have no place to discharge them to. There would be no place for them to go.

So thank you very much for your time and letting me go over a minute, Mr. Chairman. I appreciate the opportunity.

Mr. LYNCH. Thank you very much, Doctor, and thank you for your service.

Ms. GEORGE. Thank you.

Mr. LYNCH. Next up, Mr. Currie, you are now recognized for five minutes.

STATEMENT OF CHRIS CURRIE, DIRECTOR, EMERGENCY MANAGEMENT, DISASTER RECOVERY, AND DHS MANAGEMENT ISSUES, ON BEHALF OF HOMELAND SECURITY AND JUSTICE TEAM, U.S. GAO

Mr. CURRIE. Thank you, Chairman Lynch, Ranking Member Hice. It is an honor to be here today to talk about GAO's past work on biodefense. A lot of what I was going to talk about has been said, so I will try to alter this a little bit.

Biodefense is a very unique threat, and biothreats are very unique in this country. We look at lots of different threats across the government at GAO. And I think unlike cyber threats and mass shootings and things that are in our face every day, it is very difficult because the perception is that these are low-likelihood events, and thus, it makes it very difficult to maintain focus and maintain resources on these types of events. But clearly it doesn't mean that these are not serious threats and very scary threats.

The other challenge, that Dr. George mentioned, is fragmentation across the Federal Government and across all levels of government, and the private sector. We have identified, for almost a decade now, that fragmentation across large and small departments—DHS, USDA, Department of Defense—I think we said before there are almost two dozen Presidentially appointed officials that have some sort of responsibility for biodefense. They make this very, very difficult to tackle, because departments cannot tell other departments what to do, and they can't tell them how to spend their money. They also can't tell them how much money to request. This also cuts across congressional committees of jurisdiction too. It just makes it a very big challenge.

Because of this, for almost a decade, we have recommended that the Federal Government needs a large, overarching national strategy and focal point to address this issue, similar to what we have done in other areas, like cybersecurity.

In addition to the strategy itself, at the high level, we have also done work at GAO on a number of more specific biodefense-related

programs across the government, and I would like to talk about just a few of those things.

In the area of biodetection, as was mentioned in the opening statement, we have done work looking at Department of Homeland Security's BioWatch program. This is the only system we have in this country that has a goal of detecting a biothreat that is released into the air. But frankly, the system has struggled since the very beginning to do what it was intended to do. It has never done what it was intended to do and never worked as well as we have wanted it to work.

So we have made a number of recommendations over the years to try to address these issues, ultimately leading to the cancellation of this program in different ways. It is currently still in use but is going to be phased out by DHS, but the replacement situation is very uncertain and very unclear at this point, in terms of biodetection.

In the area of situational awareness, which is extremely important, which is basically how do we know what threat we are facing, how quickly, and who knows it, DHS and HHS have both struggled. On the DHS side, we have found that the National Biosurveillance Integration Center has struggled to get the data it needs and the information it needs, frankly, to be useful to its partners. We heard from the people that use it that it doesn't provide new and useful information.

And on the HHS side, it has been almost 13 years since there has been a requirement for a public health situational awareness network. That still has not been implemented. We have done work on it three or four different times in that 13 years, and recommended ways to try to implement that program. Most recently, in the recently passed legislation, required, set a deadline for its implementation again and required that HHS implement our recommendation. So HHS has just continued to struggle to implement that situational awareness program.

Laboratory safety and security, another huge issue that we and many others have identified problems with. This is an area that we have identified problems across the biodefense enterprise with all of these departments. We looked at almost every department that oversees or has laboratories and we found widespread challenges in their policies and oversight. Some policies were out of date. Some suspicious incidents were not even being reported. So we made over 33 recommendations at that time, which is a huge number, across departments. Twenty-one are still open. So some departments have made progress; others are still lagging behind.

I would also like to talk about what Dr. George mentioned, about the catastrophic incidents, and I will throw in there situations like Zika in 2016 and Ebola in 2014. What we see in these situations, and even those were not as severe as the ones we are really worried about, is it is not clear who is in charge when these situations happen, and it also not clear where the funding comes from.

We have done some work in the past looking at development of a response fund. This would be similar to what FEMA has, for example, to handle disasters when they occur. I think people vary on their views of this issue, but some people thought there needed to be some sort of fund, so we deal with these issues when they come

up, and we know exactly who is in charge of these situations, so we don't have to wait months for supplemental appropriations and things like that.

So those are just a few of the issues. I have many more things to talk about but thank you for the invitation.

Mr. LYNCH. Thank you.

Dr. Cham Dallas, you are now up for five minutes.

**STATEMENT OF CHAM DALLAS, UNIVERSITY PROFESSOR AND
DIRECTOR, INSTITUTE FOR DISASTER MANAGEMENT, ON
BEHALF OF UNIVERSITY OF MICHIGAN**

Mr. DALLAS. The potential for biological attacks and other naturally occurring pandemics is real, and of substantial national impact, and I applaud this subcommittee for addressing this issue, and thank you for inviting me here today.

It seems appropriate for my testimony to address the area of biodefense preparedness at the local level, where an appreciation of the likely in-the-field response can be discussed.

Over the last 20 years, the University of Georgia and the Medical College of Georgia—I am a professor in public health in the first and a professor of emergency medicine in the second—we have been active in research and training in biodefense emergency preparedness and response. As a result, we have had the unique experience of helping and evaluating over 700 institutional stakeholders within the state of Georgia in their relative ability to respond to a biodefense challenge at the grassroots level.

So this program in biodefense was ongoing at the turn of the century, and we got a CDC Center for Public Health Preparedness at UGA, and now is the Institute for Disaster Management that I direct.

The last 13 years, this institute has had—we have led the planning, organization, and conduct of tabletop and full-scale exercises for virtually all the hospitals, 140 of them, and then, just as important, or maybe more important, the hundreds of additional supporting institutions—the nursing homes, law enforcement, public health departments.

And so, how are we doing? One of the most important developments in this process, we have seen in Georgia, and is mimicked elsewhere in the country, is the development of health care coalitions to better coordinate biodefense response, between so many disparate institutions. It was very hospital-based for so long and now we are getting all these support institutions involved. That has been a success story.

And this was initially started in New York, quite frankly, and the success they have had there has been now duplicated in Georgia, and we hope elsewhere.

For instance, there have been many epiphanies where we get these organizations, and for the first time they divulge their plans to each other. You have got to realize these people are in competition with each other, in most cases, and all of a sudden we discover they are depending on the same resources, and they are going to be fighting over them if these events ever occurred. And so we hopefully helped them work this out in advance.

Starting in 2015, the Ebola crisis occurred, and Georgia received a lot of these patients from West Africa. And so we had to ramp up pretty quick, and we quickly realized, in our initial evaluations, that the 17 service providers, who volunteered to provide these services, were not ready. It is a pattern that expect would happen nationwide. It is just that we experienced it because we had these patients coming in.

These EMTs and docs are very bold and they are willing to go in, but you have got to train them right. For instance, we just had a tabletop last week, at the Institute in Athens, where we had all the people from all around the state that would be the actual people that would respond. And there has been progress in that. It just shows that training can work.

Now one of the most vulnerable populations in these anticipated biodefense scenarios we have found is increasing elderly populations, especially the ones in institutions, in nursing homes and assisted living facilities. There are thousands of them in Georgia alone. The vulnerabilities that have been seen in natural disasters, for vulnerable populations, very highly publicized in the recent hurricanes, as severe as they are, we can expect those to be exacerbated further, much further, when considering biodefense issues, and particularly with agents that are coming in that are microbially resistant.

Now the current system is not robust in dealing with the background. If you have ever been to these institutions they have background problems with isolating infectious disease people. And then there is evacuation. The evacuation is a nightmare. We have designed evacuation plans for many of these facilities. Nationwide it is a big problem. In fact, in most cases they are just going to shelter in place, because of the complications in trying to get them out of there.

We have researched new approaches. We have gone into the back of these ambulances and tried to ramp them up. A success story there is Georgia EMS, they were going to take three hours to transport a patient. Now we can do it in 30 minutes. That is a standard that should be expected nationwide. If we can do it in Georgia, certainly we can do it elsewhere.

Now I will tell you, if you look at a top-flight problem, and that is going to be—and we are looking at it now, is the backup power for these long-term care facilities. There are some real nightmare stories with that. Efforts are greatly needed now to prioritize and close those gaps in power backup capabilities. They have been talking about it a long time and it hasn't happened. I will just tell you, I am really worried about that one.

We have reviewed hundreds of after-action reports throughout the state, and we keep those at the Institute. Two common themes emerge—the need for additional research and training and incident command—Who is in charge? How are commands given out?—and the need for additional research in communication methodologies.

I will close with just a couple of examples. For instance, emergency codes are coming out of all of these hospitals. We found, throughout the system, they don't know what they mean. They have no idea. It is unbelievable but they don't. And we have some

plans to get off this color-code system and let's make the visitors and patients responders, instead of panicked people.

And then I will close with the mortality issue. We wrote the mass fatality plan for the state. I tell you, these rural hospitals, for them, a morgue is a little room with an air conditioner, a window unit. A lot of these facilities only have maybe a couple of weeks of money on hand. They will collapse under this pressure. And I might point out that they are also the ones that are already hard hit. This will fall hardest on the vulnerable populations.

So we have come a long way, and there is little doubt that with the increasing biological threat matrix we have a long, and I think difficult, work ahead of us.

Thank you.

Mr. LYNCH. Thank you very much.

I will now turn to questions and I yield myself five minutes for questions.

So I think because of the anthrax attacks on September 11th, I think our response was to that type of event, where terrorists or maligned actors might try to inject something like that into the population, but more recently—and I don't know, over time that has become sort of a low—there has been a probability bias that works against us focusing on that problem, because nothing has happened since 2001.

The more recent manifestations, though, are, you know, this antimicrobial resistance that we have seen in some of the hospitals. Dr. Boucher, I think you mentioned that in your remarks.

So there have been a number of assessments in terms of—the New York Times did a very, very good piece on that. It made my skin crawl—and we had a report from the Secretary-General of the United Nations that estimated that drug-resistant diseases cause at least 700,000 deaths worldwide each year, and the report noted that that figure, and I quote, “could increase to 10 million deaths per year by 2050.” And all the reports say that the figures that they are putting out are very conservative assumptions.

What is your assessment of the threat here? You know, we have heard about our preparedness, which is severely lacking, but in terms of trying to quantify the magnitude of the threat here, what are your thoughts?

Dr. BOUCHER. Thank you very much, Mr. Chairman. I think the main message is that the crisis is here, so antibiotic resistance is real, it is at all of our hospitals, it is in the community, and it is no longer if it comes. It is here. So those patients I told you about, there are more, and all my colleagues across the country are treating patients like this, and we are having the sad duty to have to send people to hospice because we have infections we can't treat. This is happening all across the country.

Mr. LYNCH. Yes.

Dr. BOUCHER. So I think that is one thing.

In terms of our response, through at least, you know, my involvement with our society for the past 15 years and the Presidential Council now for the past five years, there certainly are efforts with the National Action Plan for Combating Antibiotic-Resistant Bacteria to coordinate the efforts across the U.S. Government, and I think there has been some progress. We certainly still have a ways

to go, and, you know, the National Action Plan set out targets for what would happen by the year 2024, how resistance would decrease, how antibiotic overuse would decrease, you know, a number of hard targets, which we have not met.

We have a meeting coming up in July and we will have another report released, sort of looking ahead to the next five years as to what are the big needs, and I think that we still have some really big needs. Probably the biggest need, if we had to pick one, would be to make stewardship programs for antibiotics a condition of participation for CMS, to finalize that rule. So that rule is under consideration. I think a week or so ago it was sort of continued for another year, but we are very, very hopeful that that will be finalized. The Joint Commission has mandated that, so all Joint Commission hospitals have to have stewardship programs, and we have seen great increase across the country in the presence of stewardship programs, and it is making a difference. We need to see more.

We also have stewardship needs in the outpatient arena and CMS has a condition of participation for long-term care facilities, which are real breeding grounds for antibiotic resistance.

So those a couple of high-level thoughts, in terms of where we are.

Mr. LYNCH. Well, let me ask you about the pipeline for antibiotics, because that has to be part of the answer here, right? You mentioned how even the 42 or 46 that are in the development now, a very small number of those might address our needs. How do we incentivize that? How do we, on our end, incentivize the research and development that needs to happen?

Dr. BOUCHER. Great question. So it is true that the antibiotic pipeline is thin, and we have been making efforts for the last at least 10 years to work on, you know, resurrecting it a little bit. And while we had a little bit of good news and a few more antibiotics approved recently, we have this sort of terrible situation where the market really seems to be broken, and the bankruptcy of a company. So we are finding that the return on investment for antibiotics is just not what it needs to be, and some of the reasons are that antibiotics are given for short periods of time, we hold them—people like me hold them as much as possible to be used only when we need them for the worst infections, and, you know, the societal sort of standards are that the cost is just not that high.

So we, unfortunately, have come to the point where this company who developed an antibiotic that we really needed couldn't even afford to continue to manufacture it so we could have it on the shelf in our pharmacy for the time we need it. So that gets to incentives.

We sort of break down incentives into two groups. Push incentives are those that happen before the drug is FDA approved, and we have a good example, I think, in CARB-X, which is a public-private partnership between BARDA and several other global partners, including the Wellcome Trust and some other academic and government groups. They have successfully funded a number that at the end of this year it will be over 60 different medicines and diagnostics for antibiotic-resistant infections, and that is really great and that is helping that early phase.

The other sort of part of the story are so-called pull incentives, which cover the time after a drug is approved by the FDA, and that

is the area where we are seeing this big problem now, with the bankruptcy and maybe some more. And so there is where the DIS-ARM Act comes in, and that is one idea of a pull incentive to carve out the cost of the new antibiotic from the diagnosis-related group, the kind of bundled payment that we get in the hospital, and could be a kind of short-term, small step in the right direction.

Very importantly, that incentive is tied directly to antibiotic stewardship, so it has to be used in hospitals that have antibiotic stewardship programs, and takes it one step further, to actually requiring reporting on use of antibiotics back to the CDC, so that we will know that these drugs that are incentivized are used in the best way possible.

Mr. LYNCH. Yes.

Dr. BOUCHER. We know that more is going to be needed in the pull side, and so the concept of delinkage, that is taking the return on investment away from the volume of sales, this concept has really gained traction in ideas like a market entry reward that might be awarded to the maker of a drug that targets a really great unmet need at the time of licensing and guarantees a certain amount of return on investment over a period of, say, five years, again, tied to good stewardship and appropriate use, could be enough to kind of help get this—

Mr. LYNCH. Yes, prime the pump.

Dr. BOUCHER [continuing]. yes, get us back into a functional situation.

Mr. LYNCH. Yes. Okay. Thank you very much.

I now yield five minutes to the ranking member for questions.

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

Dr. Dallas, the biodefense preparedness, and then the defense management. How is that best coordinated on a local or state level?

Mr. DALLAS. The best thing for them to respond—and first, we have made a lot of progress. Exercises help a great deal. The one gap—I like to go back to gaps, how we improve further—is getting the physicians to come. It is hard to get them. They are busy. To get them involved in the exercise is a key factor for us. I think the key to that is through the CEOs of the hospitals. They can tell them what to do, and if they did, that would help a great deal.

Like I said before, the infrastructure support—I didn't even mention it but these things that make everything worse—the cyber vulnerability of the health care system is stunning. Just there in our local vicinity there, in your district, there have been a bunch of ransomware attacks that have taken down these health care institutions for millions of dollars. And all of this robs the infrastructure. So I would say bolstering the public health infrastructure is the answer to this, so that when it occurs—and I agree with my colleagues here that this is coming—we were talking about it before. When you say something is a low-likelihood event, it is not a straight line that we are talking about. It is low likelihood and then all of a sudden you are logarithmic and you are shooting up.

Mr. HICE. Yes. When it happens you have got to be prepared at that point.

Mr. DALLAS. You have got to be ready.

Mr. HICE. And you mentioned the health care coalitions. I am curious about that in reference to what you are talking about now,

with the exercises, assuming that means not just the hospitals and doctors but the entire health care coalition that you are talking about, which would include enforcement and a host of others involved. Is that—

Mr. DALLAS. That is right, like volunteer groups, and how to mobilize people. They can't show up at the time and help. We have to train the people. Medical Reserve Corps units. There are all sorts of ways, but it has got to be the community working together.

New York showed us the way on this, and it was really phenomenal, because it is a false multiplier of all your resources there, working together. We have seen—I saw it in Georgia, just in the last 10 years, it really explodes the capabilities, but in the end if we don't have the drugs, if we don't have the new antibiotics—I will add to the testimony that was just said, drug development is pretty big at the University of Georgia, and yet we are now telling the students coming up that the odds of you running a drug all the way through the system is 10 percent. And so these youngsters—they all look young to me now—are coming up and they are going, "I am never going to run a drug through?" And so there is just a lot of disincentivization with that, and that is a major issue.

So on the pharmaceutical end we have got to fix it. On the health care coalition we have got to continue to build it, particularly the weak links, like the nursing homes and assisted living facilities and the power backup.

Mr. HICE. And in addition to that I would think there would have to be partnership between Federal, state, and local. I mean, this is everyone working together.

Mr. DALLAS. Yes. Like we say, all disasters are local, and we sure appreciate the Federal Government's support, because the resources are massive and awesome and really impressive, although some of them, like you were describing, haven't been very efficient. But when it comes to being on the local level, it is all local, and we have to depend that they can meet these demands at the local level.

Mr. HICE. All right. Mr. Currie, let me ask you real quickly, I am sure all of you are aware that DHS has determined that fentanyl poses a significant material threat to our security. Do you agree with that assessment, by the way?

Mr. CURRIE. Yes, sir.

Mr. HICE. All of you, I am assuming, would agree with that?

So can something like fentanyl be used as a broader mass attack on the U.S.?

Mr. CURRIE. Sir, I think—I am not sure I would be comfortable answering that in a public setting. We are not actually doing any work on that specifically, but the issue of fentanyl as a drug and some of the drug concerns versus its use as a weapon of mass destruction, those are kind of two separate issues and the latter gets into classified information pretty quickly.

Mr. HICE. Okay. I totally respect that.

And my last question for now, Dr. George, you mentioned the blueprint, with 33 recommendations. Who has received those 33 recommendations, and ultimately, who is responsible to implement them?

Ms. GEORGE. So we had distributed the report throughout Congress. We issued it in 2015, though, so it has been a while. We wrote recommendations for various Federal entities, for the Administration, meaning the White House specifically, and for Congress to execute. So it depends on the recommendation.

But, you know, sir, it depends on what the topic is too. I don't think we should be leaving it to just one entity all by themselves. If the White House is not going to pick up on something, Congress certainly should. If Congress is not going to pick up on something, then the rest of the Federal Government can. You know, it is one of the beautiful things about our government. So that would be my—

Mr. HICE. That is one of the messy things about our government. Like you said, Mr. Currie, we have got like 12 different overlapping—nobody knows who is in charge, and it seems like this is something that needs to be addressed.

Thank you, Mr. Chairman. I yield back.

Mr. LYNCH. Okay. Let me stay with you, Dr. George. I know that most nations, or most all have signed this, you know, Biological Weapons Convention, basically a treaty not to purchase these agents. However, it is a different story with some of these non-state actors. And the technology has really come down in terms of the cost of acquiring or developing yourself.

What level of risk do you think that our military face, say, you know, we have got folks in Syria, we have got folks in Afghanistan, Iraq. What is the level of risk that you think is presented, for them to face what you faced in uniform?

Ms. GEORGE. Yes, sir. I, of course, think it depends on the geographic area that they are located in, but I think that they are at great risk. I think these countries, and our troops, and everybody else's troops, are at enormous risk. When you look at Syria, for example, Syria had a vibrant biological weapons program. North Korea is suspected of engaging in biological weapons development as well. And al Qaeda, ISIL, and other terrorist organizations have been very vocal about their desire to obtain or produce and use biological weapons, and they are not talking about doing that, you know, out in the country somewhere where nobody is. You have to take their desires to use biological weapons and look at who they are fighting at the same time. That puts those populations at risk and it puts our troops at risk as well.

Mr. LYNCH. Let me ask, Mr. Currie, and also Dr. Dallas. So the response in its initial phase will be local, so that means my local community health center in my neighborhood, and in a lot rural communities it is probably a local community health center. It is our docs and nurses, EMS, first responders—that is the front line of the program we have right now.

So how do we engineer our response so that we push out some of the countermeasures to that population, to our first responders, to our local health centers, to the people that are going to have to respond to this in the first instance?

Mr. CURRIE. Well, I think one thing I would like to say, this is where I think health situational awareness becomes so important. So you are right, the nurses and docs are the ones that are going to see the information the fastest and right away, but at the Fed-

eral level this is why these information networks that DHS and HHS have been developing are so critical, because the idea is that we need to have them tied into all the state and local information, to get that information as quick as possible, not just to diagnose it and understand what is going on but then quickly communicate to everybody at all those levels that need to come in and help surge and respond. Otherwise it is going to remain localized for a long period of time before the word trickles up to whoever it needs to trickle up to, and then trickles down very slowly. And that is our concern about the lack of progress on these situational awareness networks.

Mr. LYNCH. So Dr. Boucher, you are at Tufts, and, you know, we have an event like this, and, you know, as Dr. Dallas points out and Mr. Currie, the initial impact is really on the street level. How well are we equipped to connect what you are doing and the resources that you have? Are there exercises that go on here that we coordinate, you know, the local community health center with, you know, Tufts or, you know, your research arm, and, you know, the labs that are working on this?

Dr. BOUCHER. Well, I guess I can speak to what happens at the hospital. So we certainly have exercises that are ongoing and we work with the city and state Department of Public Health, which are tied into CDC. So I think we learned a lot from the Ebola experience, and it wasn't smooth when it started, but certainly I think that we have these tabletop exercises regularly and there is participation with community partners as well as a hospital like ours. You know, we are quaternary referral center, but we also communicate across town. And you know we have lots of different players in the medical world. But the state and local health departments really are the center and do a great job. And so both in sort of this really kind of dreaded disaster preparedness but also in things like the opioid epidemic, you know, we are working together in that way too.

So I think that is the vision from our CDC colleagues, is that it works local, state, health departments up to CDC and back, at least for surveillance and initial response in that regard.

Mr. LYNCH. Can you comment on that? I mean, in your initial testimony, I meant to go back to that, where you talked about, you know, opioid use contributes to this vulnerability of antimicrobial resistance. What is the connection there? I missed that.

Dr. BOUCHER. Okay. So people who inject opioids get infections because they are injecting through their skin. Even if their skin was clean they would have an increased risk of infection. And we know that patients who use opioids have a 16-times-higher risk of having an MRSA infection, which is a resistant kind of bacterial infection.

And so what we are seeing are patients like this, unfortunately—

Mr. LYNCH. Is that shared needles? Is that—

Dr. BOUCHER. It is not even. I mean, it could be. It could be worse with shared needles, but just injecting. Every time you inject in your skin—

Mr. LYNCH. Okay.

Dr. BOUCHER [continuing]. even if it is sterile there is still a risk. Skin is our most important barrier to infection. So these people are injecting over and over again, usually not in such a sterile way. But we know from good studies that these patients have a 16fold higher risk of MRSA, and that is just one kind of resistant bacteria.

But our hospitals are full of these patients, and treating them is incredibly difficult. It is heart-wrenching. These are young, otherwise healthy people, and you are talking about doing a heart valve replacement and another one and another one. It is incredible, the burden of that morbidity and mortality that we see. And so our society now has a whole group dedicated to infections in people who inject drugs, because it is such a big problem. It is almost a little bit like at the beginning of the AIDS epidemic, in terms of what we are seeing, and the burden of it, the stigma of it, and the challenges, the sort of multidisciplinary challenges in treating it.

Mr. LYNCH. Great. All right. I want to yield to the gentleman from Georgia for five minutes.

Mr. HICE. Thank you, Mr. Chairman.

Dr. George, I know that the Blue Ribbon Panel has had some meetings and has published some stuff involving the private sector being involved in the preparedness efforts, and what Dr. Dallas was talking about. Just comment a little bit of how the partnership works between the private sector and government.

Ms. GEORGE. So it depends, of course, on the topic, I guess, and I know I keep saying that.

Mr. HICE. Just an example.

Ms. GEORGE. Well, I think when it comes to pharmaceutical development, for example, the Federal Government has identified various threats, various biological threats that we would need antibiotics and other antimicrobials to address, and they need to fund those things that we don't have a market for. So that would be on the one hand.

On the other hand, the U.S. Government is not in the business of producing antimicrobials by itself, so it has to work with the private sector, and together they have to produce what is needed for the country.

Mr. HICE. Okay. So in that scenario you are talking private sector would be the corporate business sector.

Ms. GEORGE. Mm-hmm.

Mr. HICE. Okay. Coming back, Dr. Dallas, to you, the National Biodefense Structure that the President has come out with, do you see a pathway in that for better collaboration between the Federal Government, Federal agencies and state and local?

Mr. DALLAS. Yes, like what was said earlier, it was a good start and it was a long time coming, but it is a good start and I am encouraged by it, frankly. We have got to do something to bolster the private sector's incentivizations. For instance, vaccine development is a perfect example. We have almost chased the vaccine development out of the country, even when we provide incentivizations to these companies. Do you know what is their main objection? It is lawsuits. They say, "Look, we can make Tylenol or some other agent and make lots of money. The liability here is too high." And we say, "We will protect you," and they say, "I don't believe you."

And they have just withdrawn, even when offered what they say is legal protections.

Yes, I am encouraged by it. I would like to see it move forward. Like was said in other testimonies here, there are often some real latent periods. Some of them go on a long time before we see a response. But yes, I am encouraged by it. I would really like to see us incentivize these companies to move forward, and I mean right away.

Mr. HICE. Good suggestion.

All right. I want to come back to earlier you mentioned one of the things—you didn't phrase it this way—that keeps you up at night is the vulnerabilities that we have, in particular with the elderly senior community.

All right. So we have got all these facilities out here. We have got hundreds of thousands, millions of seniors living in them, and private homes, a host of different places. What is needed to bring these facilities up to standard? I mean, it sounds like an enormous task.

Mr. DALLAS. It helps that most of these facilities have isolation capabilities now, okay. It is just that they are operating on the edge. They are operating in a margin, and they don't have the incentives either to further develop these isolation capabilities. So we ought to take the isolation capabilities we have now and exercise them. Otherwise, what we will end up doing is if they get to the hospital, they will get care, and if they don't, they won't get care. And that is really dangerous.

Mr. HICE. Okay. For my help, all right, what are we talking about, isolation capabilities?

Mr. DALLAS. Well, that usually means—they are laughing over here with me—that usually means we have a little room we stick them all in.

Mr. HICE. All right. That is what I had pictured in my mind.

Mr. DALLAS. And we a \$10-an-hour person that has no training that is expected to keep them from infecting the other people, and they don't succeed, and then it spreads, and then we can't move them, because if we move them we will then contamination the bus driver and who knows who else, the personnel.

So, yes, it is to take that simplistic, very basic, almost 19th century—I shouldn't have said that—system that we have and advance it. Let's bring it up to 21st century.

Mr. HICE. Yes, I mean, and that has got to be an enormous thing. I think a little room as well. If you got an entire facility, a senior citizen facility where you have got something spreading, they are not all going to fit in one room. I mean, this is yet another disaster waiting to happen.

Mr. DALLAS. And the rural areas are where the real issues are, because they are on the edge. These are the vulnerable people. They are already on the edge, I mean, frankly, on the edge of health care access. And, boy, when this comes it is going to hit them the hardest, because they are on the edge. And then, like Mr. Currie was just saying, you know, we are the front-line people and we can't really tell what is going on. We have got to have a central organizing people to say, "Look, there is the problem," and then they come back and tell us what to do.

But I am telling you, these nursing home and assisted living facilities, particularly the ones that are on the edge now, there is where things are going to explode out of there.

Mr. HICE. Well, we would appreciate if you would fix that problem real quickly. Thank you, Mr. Chairman.

Mr. DALLAS. We will do our best.

Mr. HICE. All right.

Mr. LYNCH. I mean, that goes back to my question regarding the community health centers, because I know a lot of rural communities love their community health centers, but I am not sure that anybody on the ground within that health center is thinking about this problem, and I am not sure we have incentivized them to, you know, do that.

Mr. DALLAS. We have a lot of highly motivated people in public health departments, and people forget about them. And they are really motivated. They are just do-gooders par excellence.

Mr. LYNCH. Yes.

Mr. DALLAS. But they don't have the knowledge. Somebody at the central level has got to shoot information back to them and say, "You have got to watch. You have got to isolate, or you have got to move them out." They have got to be told, and then somebody better get down there to help them, and we are going to have to force them to have evacuation plans, and then back them up.

Mr. LYNCH. Yes. Actually, you know, so we had a suicide cluster in my neighborhood, my local neighborhood. We lost 14 young boys over about 18 months. And it was my local health center, it was the Massachusetts Department of Public Health, and then we reached out to CDC in Atlanta. So it was that whole network, sort of what you are describing, for a different type of problem, but it was very much a scramble until we got the right people in place and had an opportunity to address it.

I want to ask each of you—so you each have got about a minute and 15 seconds—what else do you think is important for the ranking member and I to know, and members of the committee to know? What else do you think is very important for us to understand? And, I mean, we have your written statements so I know you have got your top five ideas, but what else is out there that you think is lacking that we might need to address, or something that might not have percolated up in our discussion already today?

Dr. BOUCHER.

Dr. BOUCHER. Thank you very much. I will comment on a couple of things quickly. We didn't really hit that much on diagnostics, but an area where we really are on the edge, I think, of making some big advances are on diagnostic tests. So that is the ability to know if a patient has a virus or a bacteria causing their infection, or if it is a bacteria, which bacteria? If we knew that we could impact this problem of resistance, we believe, in a really meaningful way.

And so there are efforts going on in that public-private partnership I mentioned. It is funding some diagnostic companies. But there is still work to do on the path to approval and marketing and using them in our hospitals.

Another area that I don't think we probably highlighted enough was the One Health approach. So we understand that the problem of antibiotic resistance really flows between humans, animals, and

the environment, and we, in the United States, have made some good progress with our food animals, with the Veterinary Feed Directive that was passed sort of banning the use of antibiotics as growth promoters in food animals, but this problem, on a global scale is huge.

The amount of people in the world who are going to be eating meat is going up and up and up, and we know that a lot of resistance comes from the developing world to us, so this interrelationship is very important in the way we address this problem, and this is something that we are focused on in our center, in terms of research.

We are studying things like passing a resistance from your pet dog or cat to the family, and back and forth, and there are a number of issues here as well as in the environment. So I think we want to highlight that.

And then the last thing I will mention is the work force. We need a robust work force to solve this problem. We need doctors, of course, which is my bias, but also we need nurses and pharmacists and others. So we at IDSA, and others are highly engaged in things that will help us recruit and retain the best and the brightest in this field and ensure that they are remunerated adequately to stay in the field.

So thank you.

Mr. LYNCH. Excellent. Dr. George?

Ms. GEORGE. Sir, I would just mention two things in particular. We talked about information flow earlier. I think it is important for you to realize that there is an intelligence issue here as well. The intelligence community has not dedicated a whole lot of resources to this particular threat since we shut down our own offensive biological weapons program back in the 1970's. They have to step up.

But we are talking about diseases and activities that are occurring on the nonclassified side as well, so that information intelligence fusion has to happen and then information has to go up and down, so that it is usable by state and local folks.

I would also mention that it is important for you to know, if you didn't already, that the public is actually very concerned about the biological threat. One of the reasons is almost everybody has had some issue with antimicrobial resistance, of course, but many know people who have received white powder letters and packages. And also, I think it is important to understand that Hollywood has picked up on this and they keep churning out these movies that put the biological threat front and center to the public, and keeps it on their minds.

So we owe it to the constituents to actually do something about this and move, you know, the stick forward so that they feel better protected.

Mr. LYNCH. Very good.

Mr. Currie?

Mr. CURRIE. Yes, sir. I know we are running out of time so I will just limit it to—

Mr. LYNCH. No, no. You have got time.

Mr. CURRIE. Okay. I have two things. So the first thing I will say, just for you as the chairman and the ranking member, you mentioned congressional oversight. I think Dr. George mentioned

congressional oversight. We think the strategy—we are looking at it right now and we are going to report on it later this year. I think it is one of the best efforts we have seen so far, and we have been looking at this for a long time, to better coordinate biodefense.

But consistent oversight is going to be critical to keep this moving forward. We see, across government, we look at everything there is in government, at GAO, and where there is heavy oversight and heavy emphasis, progress gets made. And I think the execution of the strategy is going to be critical.

And there are going to be some really difficult things in that execution. I mentioned the prioritization of resources and budgets across so many departments. It is going to be a huge challenge to be able to look at that holistically.

Mr. LYNCH. Mr. Currie, you are actually—isn't the GAO currently reviewing the report that Dr. George referred to earlier?

Mr. CURRIE. Yes, sir. We are currently reviewing the National Biodefense Strategy to both ensure that it met the legislative requirements and also to see if it is going to be successful when it is implemented.

Mr. LYNCH. Okay.

Mr. CURRIE. And so that is exactly what I am talking about, is that, you know, it has got to be successful in the execution but it is going to be a major challenge, and it is not going to get implemented successively just by the departments without consistent congressional oversight.

Mr. LYNCH. Excellent. All right. Is that all you have got?

Mr. DALLAS. Yes, sir.

Mr. LYNCH. Okay. Dr. Dallas.

Mr. DALLAS. Yes. I want to jump right on that, along with Mr. Currie. He mentioned about congressional oversight. I will give you the perfect example, and the progress that we made in Georgia, you know, we had this influx of Ebola patients coming in, the way we were able to make progress was because there was congressional oversight language that we could get back to, that controlled how the Ebola funding was done.

Now, as we all know in here, you know, when there is government appropriations people want to send it off in all sorts of directions. But since there was very firm congressional oversight language it really made a path for us, and that is probably more than any other single factor, other than our enthusiasm and running around in the back of ambulances, was the fact that there was congressional language, and every time we got lip service, "No, the congressional language says this." And then that made us—and that is why I saw, in person, that is how we made the progress we did.

Mr. LYNCH. I do know that on the Ebola issue that we had asked a certain number of institutions to raise their hand and say, if we are in this situation, we are in. And so, you know, to those courageous institutions that volunteered their services and said, you know, "we want to be part of this and we want to step up," the only problem was when it did happen many were unprepared. They were very willing but they were woefully unprepared. And that is sort of the gap between where we want to be and where we actually are.

I also have a—I have got some housekeeping here.

Mr. HICE. Do you have—

Mr. LYNCH. Yes, yes. Absolutely. Go right ahead. I yield to the gentleman for five minutes.

Mr. HICE. I won't need five minutes. Dr. Boucher, I just have not been able to ask you the question, and I guess the one that I have remaining for you is how can we reduce the rate of unnecessary prescribed antibiotics?

Dr. BOUCHER. That is a great question. So we believe that there are a number of ways to do this. And so antibiotic stewardship, this programmatic approach to the most optimal use of antibiotics, is a great way, and it involves, you know, a program that exists in a hospital or health care system to ensure that antibiotics are used appropriately, that is, they are not used when they are not needed, and used in the best way possible when they are needed. And that is really important because using them in the best way has better outcomes.

We have learned a lot, I would say, in the first five years of the National Action Plan about what impacts behavior, why physicians give antibiotics to people with colds. We have learned that—good studies have shown that if a patient comes into the doctor's office late in the day, they are more likely to get an antibiotic than if they come early in the day. You know, there are a lot of issues at play.

And so, actually, we have recommended, at the Presidential Advisory Council, more work on implementation science. How do you actually get it to happen? How do you get people to change their behavior? And I think we are making strides. There has been some good progress in pediatrics. There was just a study this week about emergency rooms, having stewardship programs in emergency rooms. That is a place where a lot of antibiotics are handed out, and then urgent care centers are other target places.

So there is a lot of work to do, but I think that probably it is going to take a little bit of carrot and stick to make it actually work, and some better science to know what will not only work but be sustainable, because that is the other thing that we have observed, is that some programs and you get the numbers down for a while and then they trickle back up.

So I think that clearly physicians, other prescribers, all of us have a role. And then every patient has a role. I encourage patients to ask, "Do I need this antibiotic?" If every patient asked that we would be a lot further along in the trajectory.

Mr. HICE. Well, listen, I just want to personally, again, to every one of you say thank you for being here. This has been extremely informative to me, personally, and I am glad no one sneezed in here today. But this has been great and your expertise, bringing that here to Congress is very helpful. And, Mr. Chairman, to you as well, thank you for calling this hearing and putting this together. I appreciate it, and I yield back.

Mr. LYNCH. I thank the gentleman, and I would like to just followup on your excellent question.

I spent a little time, a while ago, in Honduras and in Guatemala and in El Salvador, and it was on the immigration issue, but during my visit there I learned that many of the antibiotics that we

use, the most popular ones here in the United States, penicillin and others, are available over the counter in those countries. So they sort of buy them like we buy aspirin. And so, you know, it provides a training ground for some of these germs, and it just reduces the efficacy of those antibiotics.

Is there any sort of international or regional cooperation going on with some of those countries where we could work with their health departments and maybe try to educate everyone on our effort here and how they might sort of get on the same page, and maybe we can help them with some of their issues as well.

Dr. BOUCHER. Huge issue, the over-the-counter availability of antibiotics, in much of the world. And I think the plan is the Global Action Plan for Combating Antibiotic-Resistant Bacteria. I came out of the U.N. meeting a couple of years ago. And the good news—and the WHO is sort of leading that charge, we are very much committed to, and part of that. The good news is that many countries now have an action plan. The challenges are that in many developing countries access to antibiotics is a much bigger problem than anything else. They have babies dying because they don't have access to antibiotics, and they don't have a health care infrastructure to have doctors, nurses, anybody prescribing.

Mr. LYNCH. I see.

Dr. BOUCHER. So I think it is going to take a lot to change this. Certainly our efforts in every country as part of this action plan has to have some kind of a stewardship program. It is going to be very different, right, and for some countries it might be taking antibiotics away from over-the-counter status. But it is a huge issue, that access piece, globally, is very different than what we have here in the United States.

Mr. LYNCH. Right. More complicated than I thought.

I have a little bit of housekeeping here. I want to ask unanimous consent to enter into the record a statement from the California Life Science Association that was offered by Mr. Rouda, right?

Without objection, so ordered.

Mr. LYNCH. Last, I would like to thank you all for your patience and your very, very helpful testimony and the good work that you do on a regular basis in your official capacity.

Without objection, all members will have five legislative days within which to submit additional written questions, for you, the witnesses, through the chair, which will be forwarded to the witnesses for responses. And I ask if you do receive any of these questions could you please respond as promptly as you are able.

With that this hearing is now adjourned. Thank you.

[Whereupon, at 5:32 p.m., the subcommittee was adjourned.]

