RPTR JOHNSON

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MARKUP OF:

H.R. 921, SPORTS MEDICINE LICENSURE ACT; AND

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

TUESDAY, JUNE 7, 2016

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 5:07 p.m., in Room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Guthrie, Brooks, Upton (ex officio), Green, and Pallone (ex officio).

Staff Present: Adam Buckalew, Professional Staff Member; Paul Edattel, Chief Counsel, Health; Giulia Giannangeli, Legislative Clerk, Commerce, Manufacturing and Trade; Peter Kielty, Deputy General

Counsel; Carly McWilliams, Professional Staff Member, Health; JP Paluskiewicz, Professional Staff Member, Health; Tim Pataki, Senior Advisor/Director of Member Services; Graham Pittman, Legislative Clerk, Health; John Stone, Counsel, Health; Dylan Vorbach, Assistant Press Secretary; Gregory Watson, Legislative Clerk, Communications and Technology; Jen Berenholz, Minority Chief Clerk; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Professional Staff Member; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Tim Robinson, Minority Chief Counsel; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Health Policy Advisor; Arielle Woronoff, Minority Health Counsel; and C.J. Young, Minority Press Secretary.

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

Today, the subcommittee will consider two bipartisan bills. First, H.R. 3299, sponsored by Representatives Brooks and Eshoo, Strengthening Public Health Emergency Response Act, builds upon our previous work to modernize our biodefense systems to ensure that we are well equipped to handle current and emerging biothreats, and was the subject of a Health Subcommittee hearing on May 19, 2016.

Second, H.R. 921, sponsored by the vice chair of the Health Subcommittee, Representative Guthrie, with 159 cosponsors, Sports Medicine Licensure Clarity Act, provides clarification for purposes of medical professional liability insurance as carried by sports medicine professionals who provide certain medical services in a secondary State. This bill was the subject of a hearing before the subcommittee last December 9, 2015.

In 2004, Congress enacted the Project BioShield Act, and later in 2006, enacted the Pandemic and All-Hazards Preparedness Act. In addition to establishing a strategic plan to direct research, development, and procurement of medical countermeasures, 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 no market for vaccines and therapeutics that protect against bioterror agents outside of the U.S. Government. 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 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 towards helping our preparedness for future public health emergencies, such as Ebola, by creating new incentives for developing necessary medicines and vaccines and streamlining the contracting process for medical countermeasures.

When Congress created the BARDA office, we modeled the contracting authority after DARPA to ensure the office had flexibility and could operate efficiently. Incentives are necessary to attract private investment and product development. Likewise, the contracting processes must be efficient.

I want to thank the sponsors for their bipartisan work on this critical issue. I know that you are continuing to refine this

legislation and addressing outstanding issues, but it is clear we agree on the goals of the legislation and everyone is working in good faith to move this bill.

Now a quick word about H.R. 921, the Sports Medicine Licensure Clarity Act of 2015, which was part of a Health Subcommittee hearing held last December, and would clarify medical liability rules for athletic trainers and medical professionals to ensure they are properly covered by their malpractice insurance while traveling with athletic teams to other States.

The bill is supported by leading national professional and collegiate sports organizations such as NCAA, MLB, and NFL. Also supporting is the American Medical Society for Sports Medicine, the National Athletic Trainers Association, the American Academy of Orthopedic Surgeons, and the Physicians Insurance Association of America. I support each of these bills. I urge their adoption by the subcommittee.

I yield back the balance of my time.

[The prepared statement of Mr. Pitts follows:]

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

Mr. Pitts. I now recognize Ranking Member Mr. Green for 5 minutes for his opening statement.

Mr. Green. Thank you, Mr. Chairman.

Today, we consider two bills aimed at improving our healthcare system. H.R. 921, the Sports Medicine Licensure Clarity Act, will promote the safety of our athletes by ensuring that sports team physicians, athletic trainers, and other providers can treat their patients regardless of whether they are home or away. Many medical liability insurance carriers do not offer coverage for care provided outside of the State in which the provider is licensed, making it difficult for the team healthcare professionals to maintain the adequate coverage while traveling throughout a sports season.

H.R. 921 will clarify certain aspects of the medical liability and malpractice insurance to address this issue in a targeted manner. We will also be considering an amendment to the bill to include chiropractors and physical therapists that treat athletes, which I support.

H.R. 3299, the Strengthening Public Health Emergency Response Act, aims to improve biodefense capabilities within the Department of Health and Human Services. This legislation, drawn on the recent Blue Ribbon Study Panel on biodefense, makes targeted reforms to streamline existing programs, enhance coordination between agencies, and create incentives for the market to enter the medical countermeasures market, or MCMs.

I appreciate this legislation recognizes that incentives are

needed and MCM development does not flourish without a strong commitment from the Federal Government. I support the intent, but believe the best way to incentivize MCM development is robust and stable funding like what Congress did when it created the Project BioShield Special Reserve Fund, SRF, in 2004. The availability and certainty of this 10-year fund offered a positive impact on the government's ability to attract innovator companies.

Twelve MCMs against several national security threats were delivered to the national stockpile under this program. Unfortunately, the shift to annual appropriations and less funding in general has created uncertainty where there was once confidence and there would be a market for urgently needed medical products. The amount of cooperation between government and the private sector has improved and our level of preparedness has increased over the last decade, but we must do more to meet the new challenges we face.

The current Zika virus epidemic underscores our need for a robust pipeline of vaccines and treatments effective against current and emerging threats. Last month, researchers have found a person in the United States carrying bacteria resistant to antibiotics as a last resort, an alarming development that could mean the end of the road for antibiotics. Antibiotics and other medical countermeasures are similar in that they are central to our health and national security, yet traditional market forces that drive the development of these therapies for other diseases are not sufficient to enable a robust pipeline for new treatments.

There is a clear and vital role for the Federal Government to play in order to contribute to greater public health security and ensure preparedness against biological threats and emerging infections like drug-resistant bacteria. This requires meaningful research incentives, strong public-private partnerships, transparency, and predictability and flexibility in contracting mechanisms. 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 and future threats.

H.R. 3299 puts forth a range of reforms to improve MCM development and procurement in response to emerging infectious diseases and hospital preparedness.

I want to thank the bill's sponsors for their leadership on this issue, and I want to continue to champion programs and mechanisms to spur the development of lifesaving products that protect our health and national security. We will continue to work to iron out aspects of this legislation, and I believe we can strike the right balance to best protect the health and welfare of our Nation.

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

[The prepared statement of Mr. Green follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. The chair thanks the gentleman, and now recognizes the chairman of the full committee, Mr. Upton, for 5 minutes for an opening statement.

The Chairman. Well, thank you, Mr. Chairman.

I want to recognize our former good friend who is sitting in the front row, Dr. Phil Gingrey, as well. Nice to see you, sir.

So today, our work continues to improve the public health as we consider two bipartisan bills, H.R. 3299, the Strengthening Public Health Emergency Response Act, and H.R. 921, the Sports Medicine Licensure Clarity Act.

Emergency preparedness has long been an important focus for this committee, and while it may not be a topic at the forefront of everybody's minds, our state of preparedness certainly will impact everyone in my State of Michigan and around the country. The 2014 Ebola crisis and the current Zika outbreak are just two examples of natural biological threats that we have to take very, very seriously. Threats range from the common and naturally occurring infectious diseases, such as the flu virus, to biologically engineered weapons of mass destruction. Instead of responding to each emerging threat as an individual crisis, we have to develop a comprehensive strategic framework that we can use with each new threat.

One of our main challenges in addressing biologic threats is leadership. The Blue Ribbon Study Panel noted in their bipartisan report that we need clear leadership for biodefense, saying, quote, "Centralized, effective leadership is necessary to direct and

harmonize their efforts, but because this is lacking, biodefense activities are insufficiently coordinated," end quote.

So the Strengthening Public Health Emergency Response Act, authored by my good friend Susan Brooks sitting next to me almost, and Anna Eshoo, is an important step forward to keeping Americans safe by ensuring medical countermeasures are developed and procured. This bill has GAO examine how grants are being used to make sure that goals are being met, requires BARDA and CDC to better coordinate, streamlines countermeasure procurement and contracting processes, and modifies the tropical disease Priority Review Voucher program.

We are also going to consider the Sports Medicine Licensure Clarity Act, introduced by Subcommittee Vice Chair Guthrie and Richmond, to help ensure that sports medicine professionals are adequately covered by their liability insurance while traveling with their athletic teams in other States. Current law is ambiguous as to how their insurance covers their work out of State. And this bipartisan bill acts as a solution to this often routine problem, particularly in a State like mine, whose district adjoins not only the State of Indiana, but also Illinois.

We have got two important bipartisan bills that will help improve the public health, and they deserve our continued support.

I yield back. Thank you, Mr. Chairman.

[The statement of Chairman Upton follows:]

******** INSERT 1-2 ********

Mr. Pitts. The chair thanks the gentleman, now recognizes the ranking member of the full committee, Mr. Pallone, 5 minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman. Today, the committee is considering two bipartisan bills. The first, H.R. 3299, the Strengthening Public Health Emergency Response Act, strives to help increase our emergency preparedness in two key ways. First, it would improve our medical countermeasure capabilities within the Biomedical Advanced Research and Development Authority, or BARDA, at HHS, and second, it would provide additional incentives to companies that choose to manufacture medical countermeasures. The second bill, H.R. 921, the Sports Medicine Licensure Clarity Act of 2016, would ensure that sports medicine professionals who travel with sports teams have access to their liability insurance.

And I want to thank the chairman and the staff for their willingness to work with us to address some of the concerns that have been raised regarding both of these bills. I also want to thank my colleagues and sponsors of H.R. 3299, Ms. Brooks, Ms. Eshoo, for their commitment to improving our ability to respond to biological threats. And this bill includes a lot of important provisions that will make a real difference, but I want to highlight two remaining concerns I have with it.

While I support making improvements to BARDA's contracting process, I worry about the consequences of injecting undue influence into the contracting process if the contracting office is moved to

report directly to the BARDA director. I understand this provision is intended to speed up the contracting process, but as we have heard at our hearing, BARDA's acting director opposes this change because it attempts to fix a problem that doesn't exist, and could have the reverse effect of actually slowing down the process. In fact, he explained that BARDA's average contracting timelines already take less time to complete than allowed by HHS guidelines and that the current process has a track record of success in meeting emergencies. For example, the completion of a recent contract to supply blood to Puerto Rico in response to the Zika epidemic was completed in 6 business days.

I am also worried about the consequences of further expanding the tropical disease priority review voucher, PRV, program under this bill. The PRV program was intended to incentivize research and development of drugs to prevent and treat tropical diseases that disproportionately affect poor and marginalized people. And to date, the program has not worked out as intended. There are serious unresolved issues that must be addressed before the program is expanded. For example, under the current program, sponsors were rewarded even though they did not invest in new drug research or development or did not facilitate drug access to those suffering in poor and underdeveloped countries. This conflicts with the goals Congress had when it created the program in 2007. I still believe we should explore other ways to incentivize medical countermeasure development, but expanding the tropical disease PRV program is not the answer.

I remain concerned about the impact program expansion will have

both on the value of the PRV as an incentive for drug development and on FDA resources. An influx of PRVs will reduce market value and, therefore, reduce incentives to invest in research and development of drugs to prevent or treat rare pediatric diseases, tropical diseases, and medical countermeasures. Additionally, an influx of PRVs will undermine FDA's core public health mission. Every time a PRV is redeemed, the agency must divert resources away from other critical work, which could delay approval of important human drugs.

And despite my concerns, I look forward to working with the chairman and the rest of the subcommittee to further discuss how to resolve existing issues so that we can end up with a bill that will appropriately incentivize development of medical countermeasures and best serve the American people.

The second bill, H.R. 921, the Sports Medicine Licensure Clarity Act of 2016, will ensure that sports medicine professionals are covered by their liability insurance while they are traveling with their teams. Medical licensure is State specific, so when a provider travels with a team, they are often practicing without a license and without their medical liability insurance. And this is a commonsense bill that solves a problem unique to sports medicine professionals, since they travel around the country with their teams. What is important is that it does not allow these providers to practice beyond the scope of their license or to treat athletes off the field.

I am pleased that the sponsors were able to work with the committee and stakeholders to ensure that the bill achieves the right balance.

I want to thank Mr. Guthrie and Representative Cedric Richmond for being open to these changes. And I urge members to support its passage.

And thank you, and I yield back. Thanks, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. The chair thanks the gentleman. And now recognize the vice chair of the subcommittee, Mr. Guthrie, 3 minutes for an opening statement.

Mr. Guthrie. Thank you, Mr. Chairman, for calling this markup and including H.R. 921, the Sports Medicine Licensure Clarity Act. This bill will ensure that sports medicine professionals can continue to work to provide high quality and timely health care to athletes when traveling with their teams across States.

Athletes at the high school, college, and professional levels frequently travel to different States to attend games, playoffs, or other sporting events. When the teams travel, so too do the sports medicine professionals who care for the athletes. However, there is a lack of clarity surrounding the legal protection for these sports medicine professionals who travel with their teams and are under a moral and professional obligation to treat injuries when they occur. Because of this lack of clarity, the sports medicine professionals are at great personal and professional risk because medical liability insurance carriers may not cover their work when done out of State.

This bipartisan bill has the support of many of my colleagues here today. This bill provides a much needed clarification for these sports medicine professionals as they care for athletes.

I would like to thank Chairman Pitts for including this bill today, and acknowledge the efforts of our committee staff in helping advancing this bill. I ask my colleagues to join me in supporting this bill, and I yield back the balance of my time.

[The prepared statement of Mr. Guthrie follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. The chair thanks the gentleman. And now recognize the gentlelady from Indiana, Mrs. Brooks, 3 minutes for an opening statement.

Mrs. Brooks. Thank you, Mr. Chairman.

I would like to thank my friend, Congresswoman Eshoo, and the committee staff on both sides of the aisle, who have worked together to craft a bill, H.R. 3299, the Strengthening Public Health Emergency Response Act.

This bill first and foremost puts the health and safety needs of the American people, mothers and fathers, children and loved ones, above partisan differences. Reacting to crises as they happen can and does cost countless lives and billions of taxpayers' dollars. This isn't governing, and should no longer be an acceptable strategy. There are steps we can take today to strengthen our underlying biodefense enterprise that will enhance our readiness for the next biological threat that reaches our shores, whether by an act of man or an act of nature.

This legislation ensures public safety and preparedness goals are being met by requiring the GAO to examine a grant program designed to help States, hospitals, and public agencies prepare for and respond to disasters. It also tackles our broken acquisition process by returning contracting authority to BARDA and requiring BARDA to coordinate with the CDC to stockpile efforts in order to avoid any readiness gaps or conflicting priorities. BARDA is designed to be nimble in its operations. However, the current cumbersome arrangement

has crated unnecessary confusion, delays, and uncertainty that can imperil time-sensitive national security countermeasure contracts.

We are also spurring innovation in meeting the needs of the future. This bill creates a true incentive for our private industry partners to develop medical countermeasures for threats on the Department of Homeland Security's material threat list by adding them to the PRV list. The threats on the DHS list are those pathogens designed to be of significant and real threat to our national security. By their very nature, there is virtually no private demand for these vaccines and treatments, and thus little investment to invest in researching, developing, and manufacturing these medicines. However, at no cost to the taxpayer we can keep industry engaged in the R&D of lifesaving medical countermeasures.

As we consider the ideas included in the bill today, I would encourage my colleagues to keep in mind the problem we are trying to solve together. It is our job to protect the American people. The security of our country and our citizens must be our first priority. And I look forward to working with my colleagues to pass H.R. 3299. And I urge support of the legislation

[The prepared statement of Ms. Eshoo and Mrs. Brooks follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. The chair thanks the gentlelady. As usual, all written opening statements of the members will be made a part of the record.

The chair now calls up H.R. 3299, and asks the clerk to report.

The Clerk. H.R. 3299, to amend the Public Health Service Act to ensure preparedness for chemical, radiological, biological --

Mr. Pitts. Without objection, the first reading of the bill is dispensed with. The bill will be open for amendment at any point. So ordered.

[The bill follows:]

******** INSERT 1-3 ********

Mr. Pitts. We are now on H.R. 3299, and the subcommittee will reconvene at 2:00 p.m. tomorrow. I remind members that the chair will give priority recognition to bipartisan amendments. I look forward to seeing all of you tomorrow.

Without objection, the subcommittee stands in recess.

[Whereupon, at 5:28 p.m., the subcommittee recessed, to convene at 2:00 p.m., Wednesday, June 8, 2016.]

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MARKUP OF:

HR 3299, STRENGTHENING PUBLIC HEALTH EMERGENCY RESPONSE ACT OF 2015; AND

H.R. 921, SPORTS MEDICINE LICENSURE CLARITY ACT OF 2015

WEDNESDAY, JUNE 8, 2016

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 2:00 p.m., in Room 2123 Rayburn House Office Building, Hon. Joe Pitts [chairman of the subcommittee] presiding.

Members present: Representatives Pitts, Guthrie, Shimkus, Murphy, Burgess, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Collins, Upton (ex officio), Green, Engel, Butterfield, Schrader, and Pallone (ex officio).

Staff present: Mike Bloomquist, Deputy Staff Director; Rebecca Card, Assistant Press Secretary; Karen Christian, General Counsel; Paige Decker, Executive Assistant; Paul Edattel, Chief Counsel, Health; Giulia Giannangeli, Legislative Clerk, Commerce, Manufacturing, and Trade; Jay Gulshen, Staff Assistant; Carly McWilliams, Professional Staff Member, Health; Graham Pittman, Legislative Clerk, Health; Jennifer Sherman, Press Secretary; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Sophie Trainor, Policy Coordinator, Health; Gregory Watson, Legislative Clerk, Communications and Technology; Jen Berenholz, Minority Chief Clerk; Jeff Carroll, Minority Staff Director; Elizabeth Ertel, Minority Deputy Clerk; Waverly Gordon, Minority Professional Staff Member; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Samantha Satchell, Minority Policy Analyst; Kimberlee Trzeciak, Minority Health Policy Advisor; and Arielle Woronoff, Minority Health Counsel.

Mr. Pitts. The subcommittee will come to order.

At the conclusion of opening statements yesterday, the chair called up H.R. 3299 and the bill was opened for amendment at any point.

[The Bill H.R. 3299 follows:]

**********INSERT**********

Mr. Pitts. Are there any bipartisan amendments to the bill? Are there --

Mrs. Brooks. Mr. Chairman?

Mr. Pitts. Yes.

Mrs. Brooks. Move to strike the last word.

Mr. Pitts. Chair recognizes the gentlelady from Indiana.

Mrs. Brooks. Thank you, Mr. Chairman. I would also like to recognize the gentleman for his upcoming amendment. I realized I jumped the gun here maybe and should have allowed him to introduce his amendment.

Mr. Pitts. All right, let me -- all right.

Mrs. Brooks. I yield back.

Mr. Pitts. Are there any other amendments? The chair recognizes Mr. Butterfield to offer an amendment.

Mr. Butterfield. Thank you, Chairman Pitts. I do have an amendment at the desk and I thank the gentlelady for her courtesy.

Mr. Pitts. The clerk -- do you have the amendment?

The Clerk. Amendment to H.R. 3299 offered by Mr. Butterfield.

[The amendment of Mr. Butterfield follows:]

**********INSERT**********

Mr. Pitts. Chair recognizes Mr. Butterfield.

Mr. Butterfield. Thank you, Mr. Chairman.

Mr. Chairman, let me just speak very briefly in support of my amendment to improve our nation's ability to combat public health threats by strengthening the FDA Tropical Disease Priority Review Voucher Program. We call it the PRV program.

There is no mission more important to our constituents than national security as our global society becomes more interconnected and the levels of risk increase exponentially. Research and development for medical experts and government and in the private sector are what protect us from public health threats.

Diseases like Ebola and Zika are threats to all of humanity. It is important to do our part to help our brothers and sisters around the world fight these illnesses.

The FDA's tropical disease program is a key tool in that fight. In encourages the development of treatment for dangerous diseases by prioritizing their review at the FDA.

In April, the President Obama signed into law a version of my legislation, H.R. 4400, which added the Zika virus to the tropical disease program.

Today's bill, offered by Mrs. Brooks and Ms. Eshoo, will add certain diseases which are national security threats to the PRV program.

My amendment, Mr. Chairman, strengthens the program. It

strengthens the program by reducing the chances of abuse and reforming the program to help it accomplish its mission.

Specifically, our amendment ensures that drugs qualifying for the PRV are new drugs and confirms that they will be used in people in countries plagued with tropical diseases.

My amendment preserves the value of a voucher by guaranteeing that the program is only used for its intended purpose. My amendment will also help inform our strategies to combat diseases in the future.

The amendment will result in the sharing of information about the demands for treatment of trip tropical diseases and help better understand the areas of unmet need.

It also mandates a GAO study to examine the effectiveness of the tropical disease program.

And so I thank the two members who have sponsored the legislation. I thank all of them for their bipartisan spirit and for this bipartisan bill to improve national security and reduce the threat posed by harmful diseases.

The amendment is a step in the right direction. The amendment is also a step forward for PRV programs. But there is still much to be done to improve these programs at the FDA to combat public health threats including making the pediatric PRV program permanent.

It is my hope that this amendment spurs the dialogue on how to improve all of the tools at FDA's disposal to reduce all public

health threats.

I urge my colleagues to support this important amendment and I thank the sponsors and I yield back.

Mr. Pitts. Chair thanks the gentleman.

Is there a discussion on the Butterfield amendment?

The chair recognizes the gentlelady from Indiana, Mrs. Brooks.

Mrs. Brooks. Thank you, Mr. Chairman.

I seek to strike the last word.

I would like to thank the gentleman for his amendment. I would also like to thank the gentleman for our previous work involving the Zika virus and adding it to the PRV list.

I would like to submit for the record a letter from the American Hospital Association that recognizes the crucial role that a strong emergency preparedness enterprise has in keeping our community safe.

Mr. Pitts. Without objection, so ordered.

Mrs. Brooks. Throughout this nearly year-long consideration of H.R. 3299 it has remained a top priority to ensure that we understand the incredibly unique role medical countermeasures have and how they differ from any commercial vaccine or therapeutic that goes through the FDA approval process.

From beginning to end, the challenges faced by companies in this space differ from any commercial drug that goes through the typical FDA approval pathway and it is imperative that we do not

lose sight of this fact.

Medical countermeasures research on these deadly pathogens is a high-risk endeavor and it is complicated by the fact that any vaccine or therapeutic cannot be tested in humans.

These companies who operate in this space do not operate in a vacuum and the reality is that there must be incentives in place for which the government is the sole provider.

Without true incentives in place to develop medical countermeasures such as a timely and reliable contracting process within BARDA and allowing material threats to be eligible for a priority review voucher, we weaken rather than strengthen our underlying national security enterprise and are at real risk losing our private sectors partners in this space.

These particular incentives are in the underlying bill and it does remain a top priority to maintain the integrity of this process and these programs.

I truly appreciate the hard work by both the majority and the minority staffs on the committee as well as the many industry stakeholders -- BARDA and the FDA, who have all offered their expertise.

We have continued to meet throughout this process. I am pleased to say we have accommodated many requests and I appreciate the gentleman's amendment and, of course, like the gentleman, want to strengthen the PRV process.

I understand there remains some industry issues in the

language in the amendment as potentially being too onerous. But we do look forward to working through those difficult issues and I believe that we can look forward and I will encourage support and look forward to supporting final passage of this bill and encourage our staffs to continue to work through this amendment language.

With that, I yield back.

Mr. Pitts. Chair thanks the gentlelady.

Is there further discussion on the --

Mr. Pallone. Mr. Chairman.

Mr. Pitts. Chair recognizes Mr. Pallone for five minutes.

Mr. Pallone. Thank you, Mr. Chairman.

I just, again, want to thank colleagues and sponsors of H.R. 3299 -- Mrs. Brooks and Ms. Eshoo and the chairman -- for their commitment to improving our ability to respond to biological threats and for their willingness to work through concerns that have been raised related to the BARDA contracting process and the need for a new incentive to develop medical countermeasures through expanding the use of priority review vouchers.

The amendment offered today by Mr. Butterfield reflects the bipartisan discussions to try and address these concerns and I appreciate that it is a step forward in addressing these issues.

I continue to have concerns with the change being made to the BARDA's transaction authorities. I am concerned the change will inject undue influence into the contracting process and

potentially slow down the process.

And I continue to have concerns about expanding the permanent priority review voucher program without evidence that the programs works.

It still has not been demonstrated to date that the tropical disease PRV program is incentivizing manufacturers to invest in new drug research and development.

Further, we have also heard from the administration and from numerous other stakeholders about significant issues with the current program and I am reluctant for - to further expand the program without address those underlying problems.

Under current law, there is no requirement that sponsors invest in new research to receive a priority review voucher. Of the three PRVs awarded under the tropical disease PRV program, two were to companies for drugs that were available for years outside the United States.

In one case, the drug was approved in over 80 countries before the sponsor filed an application with FDA and that application included only studies the sponsor conducted before 2007 to receive approval elsewhere.

However, under the terms of the current program FDA was forced to reward this sponsor. Recently, a PRV sold for $350 million and I want to make sure that only sponsors who are investing in new drug research and development receive such a valuable benefit.

A PRV should be an incentive to investing in new public health solutions, not a windfall to companies that do not. Another significant issue with the existing tropical disease PRV program is that it does not ensure patients, government entities and health care providers can access approved products.

Unlike the pediatric rare disease PRV program, there is no requirement that a company market a product or prove to prevent or treat a tropical disease.

International organizations such as Doctors Without Borders, the TB Alliance, Drugs for Neglected Diseases Initiative, the American Thoracic Society, among others, have reported that it is challenging and sometimes impossible to access drugs approved under FDA's tropical disease PRV program.

There is also no transparency in the current program to help us learn if and how a sponsor will make its drug available to those who we intended the program to help.

The Butterfield amendment is the first step in trying to address these two issues. First, it would a novelty requirement such as sponsors would not receive the PRV if the tropical disease product had been approved previously in another country or if the sponsor did not conduct new phase three clinical studies to support approval of a product by the FDA.

This limitation will help to ensure that we are rewarding companies who are truly investing in new R and D or products needed to treat those suffering from tropical diseases.

And second, the Butterfield amendment also would require that sponsors make publicly available a product strategy plan describing how the tropical disease product will be made available in countries where the tropical disease involved is endemic.

This requirement will provide greater transparency into how a sponsor intends to make the tropical disease product available following approval as well as ensure the sponsors are taking into consideration the need to make such product available where it is needed the most.

While I still have concerns with existing tropical disease priority review voucher program and reservations about expanding the definition of tropical disease to include material threats, I think the chairman -- I do thank the chairman for his commitment to working together to find bipartisan solutions to the issues that I have raised and I look forward to working with the chairman, the bill's sponsors, Mrs. Brooks and Ms. Eshoo, and the rest of the subcommittee to continue to address these issues before the full committee markup takes place.

And so I would urge my colleagues to vote in support of Mr. Butterfield's amendment. Thank you, and I yield back, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman. Is there further discussion on the Butterfield amendment?

If there is no further discussion, I understand we have agreed to support this amendment. The vote now occurs on the

amendment.

All those in favor shall signify by saying aye. Aye.

All those opposed, nay. The ayes have it and the amendment is agreed to.

The question now occurs on forwarding H.R. 3299 as amended to the full committee.

All those in favor say aye. Aye.

Those opposed, no. The ayes appear to have it. The ayes have it and the bill is agreed to.

The chair now calls us H.R. 921 and asks the clerk to report.

The Clerk. H.R. 921, to provide protection for certain sport medicine professionals.

[The Bill H.R. 921 follows:]

**********INSERT**********

Mr. Pitts. Without objection, the first reading of the bill is dispensed with and the bill will be open for amendment at any point. So ordered.

The chair now recognizes Mr. Guthrie for the purpose of offering an amendment in the nature of a substitute.

Mr. Guthrie. Thank you, Mr. Chairman.

I have an amendment at the desk.

Mr. Pitts. The clerk will report the amendment.

The Clerk. Amendment in the nature of a substitute to H.R. 921 offered by Mr. Guthrie.

Mr. Pitts. Without objection, the reading of the amendment is dispensed with. Mr. Guthrie is recognized for five minutes in support of his amendment.

Mr. Guthrie. Thank you, Mr. Chairman.

This amendment in the nature of substitute makes clarifying changes to the bill. In addition to clarifying the intent of the bill it includes language that ensures that sports medicine professionals treating high school athletes would be included in the bill's protections, which was always our intent.

Finally, the amendment redefines the scope of professionals who are covered under the bill. I encourage my colleagues to support the amendment and I yield back the balance of my time.

Mr. Green. Mr. Chairman, I would ask to strike the last word.

Mr. Pitts. The chair recognizes the ranking member, Mr.

Green, for five minutes.

Mr. Green. Thank you, Mr. Chairman.

I would like to take a moment to thank Representative Guthrie for working with us on H.R. 921 in such a bipartisan manner.

Since we first assessed this bill last year staff on both sides of the aisle worked diligently with stakeholders to address concerns.

The aims introduced today clarifies the intent of the bill and ensures that additional sports medicine professionals are covered.

H.R. 921 is meant to address the specific issue which is why I am glad we are taking the time to tailor and strengthen the language. Medical license requirements are a statewide responsibility. While working on this bill we were very careful not to encroach on state tort laws.

I will be happy to support the bill before us today as it strikes the right balance and respects states' ability to regulate their own professionals.

I encourage my colleagues to support the bill as amended, and I yield back my time.

Mr. Pitts. The chair thanks the gentleman. Is there further discussion on the amendment?

If there is no further discussion the vote occurs on the amendment in the nature of a substitute.

All those in favor shall signify by saying aye. Aye.

All those opposed, nay.

The ayes have it and the amendment is agreed to. Are there any other amendments to the bill? The question now occurs on forwarding H.R. 921 as amended to the full committee.

All those in favor say aye.

Those opposed, no.

The ayes appear to have it. The ayes have it and the bill is agreed to.

Without objection, the staff is authorized to make technical and conforming changes to the legislation approved by the subcommittee today. So ordered.

Without objection, the subcommittee stands adjourned.

[Whereupon, at 2:46 p.m., the committee was adjourned.]