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RPTR ZAMORA

EDTR ROSEN

MARKUP OF:

H.R. 5510, FTC PROCESS AND TRANSPARENCY REFORM ACT OF 2016;

H.R. 5111, CONSUMER REVIEW FAIRNESS ACT;

H.R. 5092, REINFORCING AMERICAN MADE PRODUCTS ACT;

H.R. 5104, BETTER ONLINE TICKET SALES ACT;

H.R. 1301, AMATEUR RADIO PARITY ACT OF 2015;

H.R. 3299, STRENGTHENING PUBLIC HEALTH EMERGENCY RESPONSE ACT OF 2015;

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

H.R. 670, SPECIAL NEEDS TRUST FAIRNESS ACT OF 2015

TUESDAY, JULY 12, 2016

House of Representatives,

Committee on Energy and Commerce,

Washington, D.C.

The committee met, pursuant to call, at 4:40 p.m., in Room 2123, Rayburn House Office Building, Hon. Fred Upton [chairman of the

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committee] presiding.

Present: Representatives Upton, Lance, Bilirakis, Brooks, Pallone, Eshoo, Tonko, and Schrader.

Staff Present: Gary Andres, Staff director; Sean Bonyun, Communications Director; Karen Christian, General Counsel; Paige Decker, Executive Assistant; Graham Dufault, Counsel, Commerce, Manufacturing, and Trade; Melissa Froelich, Counsel, Commerce, Manufacturing, and Trade; Giulia Giannangeli, Legislative Clerk, Commerce, Manufacturing, and Trade, Environment and the Economy; Jay Gulshen, Staff Assistant; Peter Kielty, Deputy General Counsel; Carly McWilliams, Professional Staff Member, Health; Paul Nagle, Chief Counsel, Commerce, Manufacturing, and Trade; Tim Pataki, Professional Staff Member; Graham Pittman, Legislative Clerk; David Redl, Chief Counsel, Telecom; John Stone, Counsel, Health; Olivia Trusty, Professional Staff Member, Commerce, Manufacturing, and Trade; Dylan Vorbach, Deputy Press Secretary; Gregory Watson, Legislative Clerk, Communications & Technology; Michelle Ash, Minority Chief Counsel, Commerce, Manufacturing, and Trade; Jen Berenholz, Minority Chief Clerk; Jeff Carroll, Minority Staff Director; Lisa Goldman, Minority Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Jerry Leverich, Minority Counsel; Tim Robinson, Minority Chief Counsel; and Andrew Souvall, Minority Director of Communications, Outreach and Member Services.

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The Chairman. The committee will come to order, and the chair will recognize himself for an opening statement.

This markup continues the committee's efforts to update government for the innovation era, boost jobs, protect the public health. We are going to consider a package of bills to modernize the FTC. We will also consider a bill regarding amateur radio, and three bills to improve public health.

Last year, we commenced our disrupter series, an ongoing series looking at the new technologies that will drive future job growth in innovation. We looked at the Internet of Things, the sharing economy, mobile payments, 3-D printing, and we even had a drone take flight during a hearing in this room. So tomorrow, we are going to examine medical apps.

We repeatedly heard that our policies are outdated and harming innovation. Our members got to work and crafted what I think is thoughtful, targeted reforms to modernize the FTC. We consolidated 11 legislative initiatives into four bills that we are going to vote on. With a vigilant eye and consumer protection, we have balanced our FTC updates with a need for consumer protection. We focused on transparency and balance. We also have solutions to restore fairness to online consumer reviews, protect consumers' rights to buy tickets to their favorite events, and strengthening Made in U.S.A. labeling.

I would note that the Consumer Review Fairness Act, a major priority for our Internet economy, enjoys bipartisan co sponsorship.

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When someone is getting ready to travel to southwest Michigan, they need to have confidence that the reviews they are reading are true, because there is not a better place to go. And I want them to know what a wonderful place my entire State is, not because someone has tinkered with the reviews, but because it really is, especially this time of year right on the lake.

We are also going to consider a bill to protect the rights of amateur radio operators. Just as the law recognizes that access to broadcast satellite communications are an important part of our national information infrastructure; so, too, should we recognize the role of amateur radio. Especially important, as amateur radio operators can serve a crucial role in providing communications in the wake of natural disasters and other times when commercial communications networks might be unavailable.

On the health front, we have had good success in getting important public health solutions across the finish line. We look to build upon our success as we consider three more bills. The Sports Medicine Licensure Clarity Act would ensure that team doctors, trainers, and other licensed healthcare professionals are covered by their malpractice insurance when providing care to their athletes outside of their primary State.

Special Needs Trust Fairness Act would extend the special needs trust exemption to allow non-elderly folks with disabilities to establish a special needs trust on their own behalf. If enacted,

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special needs trust established by a non-elderly disabled individual would no longer be considered an asset in determining that individual's eligibility for Medicaid.

I have an amendment in the nature of a substitute for the bill, which will include two very targeted policies: One, which would require a more -- no, we are not going to do that. One would extend the Medicaid's tobacco cessation benefit to women for the first day of their baby's life. Overall, the accrued savings will be deposited in the Medicaid Improvement Act.

And lastly, we will consider the Strengthening Public Health Emergency Response Act of 2016, which would examine how we can improve our emergency preparedness programs better, coordinate our strategic national stockpile, and create a new priority review voucher program for incentivizing medical countermeasures to ensure that our Nation is prepared in the event of an attack. Look forward to advancing all these important bills.

I recognize the gentleman from New Jersey for an opening statement for 5 minutes.

Mr. Pallone. Thank you, Mr. Chairman.

This is our last chance to move meaningful legislation through the committee process before the extended July/August recess. Unfortunately, instead of working together to help our constituents, we are faced today with a majority systematic attempt to dismantle the one agency, the Federal Trade Commission, whose mission is to protect

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consumers from unscrupulous actors in the marketplace.

The GOP's process bill, H.R. 5510, does not help innovation; instead, it makes consumers less confident that they are being protected, and therefore, less likely to trust the newest technologies. This morning, at our FCC oversight hearing, I pointed to a recent study by the National Telecommunications and Information Administration that found 84 percent of Americans are worried about their privacy and security online. Half of the household surveyed are so worried about their privacy that they limit their online activities.

And it is not only Democrats who have voiced concern. Last month, at a hearing on privacy and Internet service providers, the lead Republican witness raised concerns about this bill. That hearing also highlighted the majority's unique ability to speak out of both sides of its mouth at the same time. During the hearing, you heard my Republican colleagues and the Republican witnesses continually praise FTC's enforcement and oversight. Now, this month, the majority seeks to move a bill that undermines the FTC's enforcement abilities.

It is ironic that my colleagues would praise the FTC and its expertise, while at the same time, advancing a bill through the committee that would cut the FTC's legs out from under it. The Republican process bill before us today would gut the FTC of even its limited authorities. Among its numerous deficiencies, this bill would weaken FTC's major enforcement tool by capping consent orders at 8 years. It would also create major loopholes that allow bad actors

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to avoid enforcement by relying on outdated or irrelevant guidance or by using stall tactics to force automatic closures of investigations.

Mr. Chairman, marking up this bill today is frankly a waste of time. We should be focusing on bills that have bipartisan support and can be signed into law, not those that are election-year schemes that may not make it to the House Floor, let alone make it through the Senate.

Today, we are also considering seven other bills, including H.R. 5111, the Consumer Review Fairness Act, the bill that will protect the free speech of online reviewers, and I support this bill. Companies should not be including non-disparagement clauses in their terms of service agreements.

I also support H.R. 5104, the Better Online Tickets Act, that prohibits bots, sophisticated ticket-buying software that can buy up hundreds of tickets in a matter of minutes, or even seconds, long before a consumer even gets around to looking at the ticket-selling Web site. However, as we heard in testimony, bots are only a small part of the ticketing challenges facing consumers, and that is why I supported moving Mr. Pascrell's Better Oversight of Secondary Sales and Accountability in Concert Ticketing, or the BOSSACT, which seeks to address a number of transparency issues.

Regarding H.R. 5092, the Reinforcing American-Made Products Act, I am sympathetic for the cause for a national standard for what is Made in the U.S.A., but I do not want to diminish State enforcement tools, and therefore, I can only support final passage if it includes the

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amendment that Mr. Kennedy will offer to ensure that States can enforce the national standard.

We are also considering H.R. 1301, the Amateur Radio Parity Act. Amateur radio provides essential services in times of emergency. I support the bipartisan amendment in the nature of a substitute negotiated by Chairman Walden and Ranking Member Eshoo. It addresses concerns raised by stakeholders while providing amateur radio services with better access to build facilities.

As to the health bills, while I support the intent of H.R. 3299, I have serious concerns about creating a new permanent priority review voucher program absent evidence that this incentive is needed or works. GAO has conducted only one study of an existing priority review voucher program. To date, we have not seen evidence that the program works as intended, but we are aware of serious and unresolved issues with existing PRV programs.

These issues have allowed certain manufacturers to receive this valuable incentive without any new research or the requirement to make their product available to those in need. Making such an incentive permanent will only perpetuate known failures in existing PRV programs. It will also further devalue the incentive for other important development areas, such as neglected tropical and rare pediatric diseases.

I also have concerns with delegating contracting authority directly to the BARDA director. As the acting BARDA director made

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clear at the hearing, the data does not support the need for this change, and this structure raises program integrity issues.

I support H.R. 929, the Sports Medicine Licensure Clarity Act, that will ensure the sports and medicine professionals are covered by the liability insurance while they are traveling with their teams. This is a commonsense bill that solves a problem unique to sports and medicine professionals since they travel around the country with their teams.

The bill does not allow those providers to practice beyond the scope of their license or to treat athletes off the field. I am pleased that this sponsor is able to work with the committee and stakeholders to ensure that the bill achieves the right balance.

And finally, H.R. 670, Special Needs Trust Fairness Act, is bipartisan legislation that would allow individuals to set up special needs trusts for themselves without a core petition. This is also a commonsense policy that will help individuals with disabilities. I have championed this legislation for multiple Congresses and believe it should be enacted into law. However, this bipartisan bill has been amended, but our policies have not been considered by our members, and this is not transparent and circumvents the process that is in place for a reason.

I do not believe these policies have been thoroughly reviewed, and therefore, I simply cannot vote in favor of this legislation moving forward if these extraneous policies are adopted. And I hope we can

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work together to make the necessary changes.

Thank you, Mr. Chairman.

The Chairman. Thank you.

Do other members wish to make an opening statement?

The gentleman from New Jersey is -- no.

The gentlelady from California is recognized for 3 minutes.

Ms. Eshoo. Thank you, Mr. Chairman. And thank God everything is all right, and the lockdown is over without any incident. I appreciate you calling this markup on the several bills that we are taking up to address the authorities and the processes of the Federal Trade Commission legislation on amateur radio parity, as well as legislation to strengthen our biodefense.

I have a keen interest in that area, having authored the original legislation which became law with Richard Burr, and it has been a pleasure to work with my colleague from the other side of the aisle, Susan Brooks, on this, to bring it up to date.

I welcome the committee's consideration of H.R. 5111, the Consumer Review Fairness Act. This is going to prevent businesses from trying to silence their critics on online review Web sites. It is an important bill that I hope everyone will support. However, honest reviews can be silenced through other types of lawsuits that are not covered by this bill.

That is why I have authored broader legislation called the SPEAK FREE Act to crack down on meritless lawsuits that are intended solely

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to silence critics. These lawsuits threaten the First Amendment, and open communication on the Internet. My hope is that the SPEAK FREE Act will move jointly with the bill before us today.

I am also pleased we have reached an agreement on the Amateur Radio Parity Act. This bill will make it easier for amateur radio operators to install the antennas they need to broadcast over the air while also providing homeowners association with the flexibility to establish reasonable rules regarding the size and the appearance of these antennas.

I am pleased to have worked on the substitute amendments sponsored by Chairman Walden, Kinzinger, and myself, and I think it is a good example of a bipartisan compromise and cooperation, and I think that we have done a good job on that.

I do have concerns with H.R. 5092, the Reinforcing American-Made Products Act, because the bill would undermine California's very strong "Made in the U.S.A." labeling law, which is really the gold standard in our country. And it is synonymous with safe and quality-made products. So I really oppose -- strongly oppose any preemption of California's laws, and in this case, it is a -- California has a superb one.

I am also disappointed that the committee has chosen to move forward with the FTC Process and Transparency Reform Act, because it weakens and undermines the FTC's authority to protect consumers under the guise of process reform. It is no coincidence that the majority

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has advanced legislation to transfer broad consumer protection authority from the FCC to the FTC while simultaneously working to gut the FTC's ability to enforce these final protections. So this is a little bit of agency cross-dressing here. So I just -- I can't support that.

But finally, Mr. Chairman, I want to thank you for your leadership in bringing up H.R. 3299, and that is the Strengthening Public Health Emergency Response Act. We all know that, as Members, our highest responsibility is the national security of our Nation, and this includes biodefense.

This bill makes critical updates to the Biomedical Advanced Research and Development Agency, which we call BARDA, the procurement of medical countermeasures, which will provide Congress with the useful information on State, local, and hospital preparedness programs, and review voucher programs at the FDA, and creates a new incentive program to encourage the development of medical countermeasures. And we absolutely need to do that.

And these efforts that my colleague, Mr. Pallone, mentioned, really, if you vote for those, you are going to be gutting the bill, absolutely gutting the bill. And I don't know why they are having a problem with it from -- I think it is just a tug of war inside of a small agency.

At any rate, I want to especially thank my colleague, Mrs. Brooks, and her staff. They have been just absolutely terrific to work with,

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serious-minded, important contributions, tireless efforts in moving the bill to the finish line.

So thank you, Mr. Chairman, and I yield back.

Mr. Lance. [Presiding.] I thank the gentlelady.

The chair reminds members that pursuant to the committee rules, all members' opening statements will be made part of the record.

Are there further opening statements? Mr. Bilirakis.

Mr. Bilirakis. Thank you, Mr. Chairman.

And I want to thank Chairman Upton for holding this very important markup.

Today, we consider eight bills that will benefit our seniors, consumers, and businesses across the Nation. I am especially proud we will consider my FTC REPORTS Act as part of the larger Federal Trade Commission Process and Transparency Reform Act. This bill will bring about a more transparent and accountable FTC, a goal this committee has had for a long time.

My FTC REPORTS Act would require the Federal Trade Commission to submit an annual plan to identify projected activities including policy priorities, any rulemakings, plans to develop guidelines, efforts to restructure the Commission, and activities related to the Commission's efforts to combat fraud against individuals over the age of 65.

By requiring annual reports from the FTC, we may better identify areas of potential reform and ways we can help protect consumers, especially seniors. There have been far too many cases of exploitation

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of our elderly. Many of my constituents have fallen victim to fraudulent behavior and scams. According to the National Adult Protective Services Association, an estimated one in five adults over the age of 65 have reported financial exploitation. Moreover, only one in 44 cases of financial abuse were reported to the authorities.

Unfortunately, these bad actors target our Nation's seniors, and the results can be devastating to these individuals and their families. The Federal Trade Commission must work to better address this problem. The legislation before us today gives us the opportunity to help improve and modernize the FTC. These bills will provide certainty for all Americans. My bill helps to better protect our seniors and their families, and I am proud to continue working to empower our consumers.

I want to thank Chairman Upton again, and Chairman Burgess, for including my bill in the larger reform act.

And I yield back. Thank you.

Mr. Lance. Thank you very much, Mr. Bilirakis.

The chair now recognizes Mr. Tonko of New York.

Mr. Tonko. Thank you, Mr. Chairman.

And I rise in strong support of H.R. 5104, the Better Online Tickets Sales Act, better known as the BOTS Act, on which I joined in introducing with my colleague and good friend from Tennessee, Mrs. Blackburn.

This bill would target the unfair practice of using software bots by scalpers to automate the process of purchasing event tickets from

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online vendor platforms. As was amply demonstrated at the legislative hearing, the current lack of any Federal statute to deter the practice of using bots has turned the ticket industry in the United States into a fixed game.

For instance, on December 8 of 2014, a single broker used a bot to purchase over 1,000 tickets for a U2 concert at Madison Square Garden within the first minute of sales. By the end of that day, the same broker and one other had amassed more than 15,000 tickets to U2's shows across North America.

According to an exhaustive investigation by New York State's Attorney General Eric Schneiderman, tickets that are purchased in this manner are then resold on secondary markets at an average of 49 percent above face value, though there are plenty of examples where the markup was more than 1,000 percent.

The people in the capital region of New York that I represent, and those across the country work too hard to save enough money to see a performance or a game. They shouldn't be prohibited from buying a ticket online because the computer program beats them to the punch.

By following the example set by States like New York, where unlawful ticket brokers have had to pay stiff penalties for their actions, we can start to reel in these unfair practices. The BOTS Act takes a cue from my home State by prohibiting the intentional use or sale of bots software, as well as barring any knowing sale or use of tickets acquired by bots for entry into a concert or event.

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This legislation would establish civil penalties for this behavior on a national level, instructing the FTC or the attorney general of a State to bring civil action against any person found in violation. There is clearly still much that can be done to protect consumers within the ticket market, but I believe the BOTS Act represents an excellent first step in bringing this industry out of the shadows and holding shady ticket brokers accountable for their actions.

With that, I thank you, Mr. Chair, and I yield back the balance of my time.

Mr. Lance. Thank you, Mr. Tonko.

I am advised that Congresswoman Brooks wishes to participate, and she is on her way and is slightly delayed because of the lockdown, and we will pause to wait for Congresswoman Brooks of Indiana. And then that will be it, or so I am advised.

Thank you very much. The hearing will reconvene and the chair recognizes Congresswoman Brooks from Indiana.

Mrs. Brooks. Thank you, Mr. Chair. I want to thank you for the indulgence of waiting a few moments.

First of all, I want to thank Chairman Upton for his dedication in recognizing this matter as a priority and his dedication to craft policy that will benefit public health in the face of biological threats that occur in nature as well as those being manufactured by terrorist groups.

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I also want to thank my partner on this bill, Congresswoman Eshoo, who, as the author of the original Project Bioshield in 2006, brings a wealth of experience and insight that demands our utmost respect.

Mr. Chairman, to illustrate the problem that we face, let's consider a group of 20 people. In the event of an outbreak of smallpox, six out of the 20 will die. If a terrorist group attacks the 20 people with nerve agents, 13 will perish; if the 20 people were infected with Ebola, 18 would lose their lives; and if a cyanide or multidrug-resistant anthrax attack, it would leave all 20, the entire population, dead.

When faced with threats like these, these are only a few of the 13 deadly pathogens considered material threats by our U.S. national security community. We are in very real danger because of all of these threats --because of all of these threats, we are woefully unable to handle these types of threats.

Like many of my colleagues here today, I believe that Congress' top mission, and one which I pledged to uphold earlier in my career, when I was appointed as U.S. attorney and sworn in after 2001, it is our duty to defend our country against all threats, foreign and domestic.

When crafting those words, our Founders couldn't have imagined the world we live in today where entire populations could be wiped out by threats invisible to the naked eye and paid by their fellow man and able to be transported around the world in a matter of hours.

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The bill before us, H.R. 3299, takes significant steps to strengthen our underlying emergency preparedness enterprise by coordinating our medical countermeasures stockpiling efforts, reforming contracting procedures at BARDA, creating a new priority review voucher program for these material threats.

Returning that contracting authority to BARDA, as is intended in statute, will ensure faster development of critical medical countermeasures, strengthen our relationship with private sector partners, and cut through bureaucratic red tape without creating new burdens for HHS or costing taxpayers a dime.

Creating a new priority review voucher program for agents and deadly pathogens, identified on the DHS material threat list, will spur innovation and the development of effective medical countermeasures. This is vital because there is not a commercial market for these vaccines and treatments, and thus, little incentive for private industry to invest in researching, developing, and manufacturing these medicines. This bill fixes that by creating a true incentive for our private sector partners to develop medical countermeasures without adding to our deficit.

Legislation authored by Senator Burr and Senator Casey closely mirrors H.R. 3299. It has already passed out of the Senate Health Committee with full bipartisan support. This is not now and has never been a partisan issue, and I am so very pleased that the committee will be taking up this important legislation.

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With that, I urge my colleagues to support this legislation and yield back.

Mr. Lance. Thank you very much.

Are there other members who wish to speak opening statements?

Seeing no one, this concludes the opening statements. The committee will reconvene tomorrow at 4:30 in the afternoon, not 2:00, and 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 committee stands in recess.

[Whereupon, at 5:05 p.m., the committee was recessed, to be reconvened at 4:30 p.m. on Wednesday, July 13, 2016.]

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6 MARKUP OF:

7 H.R. 5510, FTC PROCESS AND TRANSPARENCY

8 REFORM ACT OF 2016;

9 H.R. 5111, CONSUMER REVIEW FAIRNESS ACT;

10 H.R. 5092, REINFORCING AMERICAN MADE

11 PRODUCTS ACT;

12 H.R. 5104, BETTER ONLINE TICKET SALES

13 (BOTS) ACT;

14 H.R. 1301, AMATEUR RADIO PARITY ACT OF 2015,

15 AND AN AMENDMENT IN THE NATURE OF A

16 SUBSTITUTE TO H.R. 130;

17 HR 3299, STRENGTHENING PUBLIC HEALTH

18 EMERGENCY RESPONSE ACT OF 2015;

19 H.R. 921, SPORTS MEDICINE LICENSURE CLARITY

20 ACT OF 2015; AND,

21 H.R. 670, SPECIAL NEEDS TRUST FAIRNESS ACT

22 OF 2015.

23 WEDNESDAY, JULY 13, 2016

24 House of Representatives

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1 Committee on Energy and Commerce

2 Washington, D.C.

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6 The committee met, pursuant to call, at 4:00 p.m., in Room
7 2123 Rayburn House Office Building, Hon. Fred Upton [chairman of
8 the committee] presiding.

9 Members present: Representatives Upton, Barton, Whitfield,
10 Shimkus, Pitts, Walden, Murphy, Burgess, Blackburn, Scalise,
11 Latta, McMorris Rodgers, Harper, Lance, Guthrie, Olson, McKinley,
12 Kinzinger, Griffith, Bilirakis, Johnson, Long, Ellmers, Bucshon,
13 Flores, Brooks, Mullin, Hudson, Collins, Cramer, Pallone, Rush,
14 Eshoo, Green, DeGette, Capps, Doyle, Schakowsky, Butterfield,
15 Matsui, Castor, Sarbanes, McNerney, Welch, Lujan, Tonko, Yarmuth,
16 Clarke, Loeb sack, Schrader, Kennedy, and Cardenas.

17

18 Staff present: Gary Andres, Staff Director; Will Batson,
19 Legislative Clerk, Energy and Power; Mike Bloomquist, Deputy
20 Staff Director; Sean Bonyun, Communications Director; Elena
21 Brennan, Staff Assistant; Rebecca Card, Assistant Press
22 Secretary; Karen Christian, General Counsel; James Decker, Policy
23 Coordinator, Commerce, Manufacturing, and Trade; Paige Decker,
24 Executive Assistant; Graham Dufault, Counsel, Commerce,

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1 Manufacturing, and Trade; Paul Edattel, Chief Counsel, Health;
2 Melissa Froelich, Counsel, Commerce, Manufacturing, and Trade;
3 Giulia Giannangeli, Legislative Clerk, Commerce, Manufacturing,
4 and Trade; Jay Gulshen, Staff Assistant; A.T. Johnston, Senior
5 Policy Advisor; Peter Kielty, Deputy General Counsel; Carly
6 McWilliams, Professional Staff Member, Health; Paul Nagle, Chief
7 Counsel, Commerce, Manufacturing, and Trade; Tim Pataki,
8 Professional Staff Member; Graham Pittman, Legislative Clerk;
9 Mark Ratner, Policy Advisor to the Chairman; David Redl, Chief
10 Counsel, Telecom; Michelle Rosenberg, GAO Detailee, Health; Chris
11 Santini, Policy Coordinator, Oversight and Investigations; Dan
12 Schneider, Press Secretary; Olivia Trusty, Professional Staff,
13 Commerce, Manufacturing, and Trade; Dylan Vorbach, Deputy Press
14 Secretary; Gregory Watson, Legislative Clerk, Communications and
15 Technology; Michelle Ash, Minority Chief Counsel, Commerce,
16 Manufacturing, and Trade; Jen Berenholz, Minority Chief Clerk;
17 Jeff Carroll, Minority Staff Director; Elizabeth Ertel, Minority
18 Deputy Clerk; David Goldman, Minority Chief Counsel,
19 Communications and Technology; Lisa Goldman, Minority Counsel;
20 Waverly Gordon, Minority Professional Staff Member; Tiffany
21 Guarascio, Minority Deputy Staff Director and Chief Health
22 Advisor; Jerry Leverich, Minority Counsel; Dan Miller, Minority
23 Staff Assistant; Caroline Paris-Behr, Minority Policy Analyst;
24 Rachel Pryor, Minority Health Policy Advisor; Tim Robinson,

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1 Minority Chief Counsel; Samantha Satchell, Minority Policy
2 Analyst; Matt Schumacher, Minority Press Assistant; Ryan
3 Skukowski, Minority Senior Policy Analyst; Andrew Souvall,
4 Minority Director of Communications, Outreach and Member
5 Services; Kimberlee Trzeciak, Minority Health Policy Advisor; and
6 Megan Velez, Minority FDA Detailee.

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1 The Chairman. The meeting will come to order. So I want
2 members and folks watching to know sort of what the agenda is.
3 We delayed this Markup because of a Bill on the floor. That Bill
4 is almost done. They're in the motion to recommit. It's going to
5 be a little while before votes are called on the floor, so we'll
6 work until those votes are called, which we'll recess until after
7 the votes are done. And immediately following the recorded votes
8 on the House floor we'll come back to continue the Markup, but
9 we will hold or roll, I guess you could say, roll the votes ordered
10 between that point and 8:00 p.m. so that people can do dinner,
11 whatever they've got planned. And at 8:00 we will then have a call
12 of the roll on the votes ordered at that point, and we will
13 continue. And since we're going to be in until midnight or 1:00,
14 it's my understanding on the floor, we'll continue so that we don't
15 have to be here tomorrow in the Markup, assuming that we get done
16 by then, which I think we can. If I had to guess, I don't think
17 we'll be in maybe past 9:00 or 10:00 on the Bills that we've got
18 going, and maybe that will cause some of the things to move a little
19 bit faster.

20 So that's the agenda, so you're free not to be here, but
21 knowing that votes will be called at 8:00 on those amendments or
22 Bills that a vote is asked -- a recorded vote is asked for. So,
23 the Chair would first call up H.R. 1301, and ask the Clerk to
24 report.

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[The Bill H.R. 1301 follows:]

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*****INSERT 1*****

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1 The Clerk. H.R. 1301, to direct the Federal Communications
2 Commission to extend to private land use restrictions its rule
3 relating to reasonable accommodation of amateur service
4 communications.

5 The Chairman. And without objection the first reading of the
6 Bill is dispensed with. The Bill will be open for amendment at
7 any point.

8 The Chair would recognize Mr. Walden.

9 Mr. Walden. Thank you, Mr. Chairman. I have a --

10 The Chairman. Offering an amendment in the nature of a
11 substitute?

12 Mr. Walden. I have an amendment in the nature of a substitute,
13 yes.

14 Mr. Smith. And the Clerk will report the title of the
15 amendment.

16 The Clerk. Amendment in the nature of a substitute to H.R.
17 1301 offered by Mr. Walden.

18 [The Amendment offered by Mr. Walden follows:]

19

20 *****INSERT 2*****

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1 The Chairman. And without objection the reading of the
2 amendment is dispensed with, and the gentleman is -- Staff will
3 distribute the amendment, and the gentleman is recognized for five
4 minutes in support of his amendment.

5 Mr. Walden. I thank the Chairman, and I want to thank Ms.
6 Eshoo and her team, our team, Mr. Kinzinger's team, everybody has
7 worked together on this, and I'll talk more about that in the
8 future. But we offer this as, in effect, a joint amendment, a
9 bipartisan effort here.

10 There are about 730,000 amateur radio operators in the United
11 States. I should know, I'm actually one of them. The rest of you
12 all pretend to be hams, but I'm actually a licensed one. Amateur
13 radio operators utilize a variety of radio frequencies to
14 communicate across town, across the country, around the world,
15 and even into outer space. Amateur radio operators also occupy
16 an important role in the emergency response system. They are often
17 able to establish communications during natural disasters when
18 commercial networks are unavailable.

19 Unfortunately, Mr. Chairman, the law doesn't afford amateur
20 radio operations the same level of freedom to operate that are
21 enjoyed by consumers of other radio services. For example, the
22 FCC's regulations ensure consumer's access to direct broadcast
23 satellite services. You can have a satellite dish. H.R. 1301 seeks
24 to provide hams with the certainty that like DBS satellite

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1 customers, they will be able to enjoy access to communication
2 service of their choice regardless of where they live.

3 This Bill has come a long way since it was first introduced.
4 Proud to say that thanks to the hard work of our Staff and members
5 of the amateur radio and community association communities today
6 H.R. 1301 enjoys broad support with this manager's amendment. This
7 bipartisan amendment in the nature of a substitute represents
8 months of meetings, hard work, compromise to ensure the amateurs
9 are protected but not at the expense of the rights of Americans
10 living in deed-restricted communities. We found a good balance
11 here.

12 The amendment guarantees that even in deed-restricted
13 communities, amateur radio operators are able to use an effective
14 outdoor antenna. Without an effective antenna, amateur radio
15 operators are severely limited, so this amendment ensures that
16 amateurs are free to pursue their passion wherever they live.

17 This amendment also respects, though, the rights of
18 Americans, including amateur radio operators who have chosen to
19 live in deed-restricted communities. Millions of Americans live
20 in communities like these, and choose to set their own esthetic
21 and other rules. This is a knowing choice, and must be respected.
22 This amendment does just that. While it's rare to have the two
23 groups with opposing viewpoints walk away from legislation happy,
24 by golly, I think we've done it here.

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1 Both the Amateur Radio Relay League, that's the Association
2 of HAM Radio Operators, and the Community Association Institute
3 that represents the nation's community associations have written
4 us letters to the subcommittee in support of this amendment.

5 So again, I'd like to thank our Staff, the Staff of Mr.
6 Kinzinger, the Ranking Member Ms. Eshoo, the Amateur Radio Relay
7 League, the Community Associations Institute all for their hard
8 work and expertise which allows us to move forward with this
9 legislation. Compromise memorialized in our amendment in the
10 nature of substitute represents the best of what our committee
11 can do when we work together, bipartisan compromise that meets
12 the needs of all parties involved. I thank my colleagues and urge
13 you to support this amendment in the nature of a substitute. And
14 I'd yield to my friend and colleague from California, if she would
15 like to do it that way, Ms. Eshoo, for comments on our joint
16 amendment.

17 Ms. Eshoo. I thank the gentleman. I'm glad that we've come
18 to an agreement on this Bill. When we originally considered it
19 in the subcommittee, I was worried that it would violate the rights
20 of homeowners associations, and Chairman Walden assured me that
21 he would work with me to address the concerns before the Bill was
22 marked up by the Full Committee, and he did. So we found a balance
23 that works for all of the stakeholders, and the Bill is now
24 supported by the Community Associations Institute, and the

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1 Amateur Radio Relay League. So I guess when you have both of those
2 groups as the bookends of the effort, you know that it's been
3 worked out. So I thank Mr. Walden, I thank Mr. Kinzinger, and I
4 recommend to all of our colleagues, both sides of the aisle, that
5 they support it. It's a good Bill, it's a good worked-out Bill.

6 Mr. Walden. And with that, I'd yield -- -

7 Ms. Eshoo. Thank you.

8 Mr. Walden. -- to the gentleman from Illinois, Mr.
9 Kinzinger, for comments.

10 Mr. Kinzinger. Well, thank you, Mr. Chair. I just want to
11 thank the Ranking Member, I want to thank you, Chairman Upton,
12 Staff, everybody for working together on this for the associations
13 involved. This is a good amendment, strikes the right balance,
14 and just goes to show how legislating may take a little hard work,
15 but we can always ultimately get there. So I thank you, and I yield
16 back to you.

17 Mr. Walden. And in the nature of returning time to the
18 committee to move forward on our other business, I yield back with
19 10 seconds left.

20 The Chairman. The gentleman yields back. Other members
21 wishing to speak? Seeing none, the vote occurs on the amendment
22 in the nature of a substitute. All those in favor say aye.

23 [A chorus of ayes]

24 The Chairman. Those opposed say no. The ayes have it, the

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1 ayes have it. Amendment in the nature of a substitute is agreed
2 to.

3 Are there further amendments to the Bill? Seeing none, the
4 question now occurs on favorably reporting H.R. 1301 as amended
5 to the House. All those in favor so signify by saying aye.

6 [Chorus of ayes]

7 The Chairman. Those opposed say no. The ayes appear to have
8 it, the ayes have it, and the Bill is favorably reported.

9 The Chair would now call up H.R.5111 and ask the Clerk to
10 report.

11 [The Bill H.R. 5111 follows:]

12

13 *****INSERT 3*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 5111, to prohibit the use of certain clauses
2 and form contracts that restrict the ability of a consumer to
3 communicate regarding the goods or services offered in interstate
4 commerce that were the subject of the contract and for other
5 purposes.

6 The Chairman. And without objection the first reading of the
7 Bill is dispensed with. The Bill will be open for amendment at
8 any point. The Staff -- oh, the Bill has been called up, and are
9 there any bipartisan amendments to the Bill? Are there any
10 amendments to the Bill?

11 Mr. Burgess has an amendment at the desk.

12 [The Amendment offered by Mr. Burgess follows:]

13

14 *****INSERT 4*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Burgess. Yes, Mr. Chairman. This -- -

2 The Chairman. And the Staff -- the Clerk will report the title
3 of the amendment.

4 The Clerk. Amendment to H.R. 5111 offered by Mr. Burgess.

5 The Chairman. And the amendment will be considered as read.

6 The Staff will distribute the amendment, and the gentleman is
7 recognized for five minutes in support of his amendment.

8 Mr. Burgess. Thanks, Mr. Chairman. The amendment would add
9 a savings clause to the Consumer Review Fairness Act clarifying
10 that the provisions of the Act do not supersede or impair the FTC
11 Act, or other federal laws. The Federal Trade Commission suggested
12 we include such a savings clause, and we are happy we've been able
13 to accommodate this in a bipartisan way.

14 We also add "is," after "or," in a provision of the Rule of
15 Construction. This corrects a drafting issue where the
16 second-half of the sentence could be read as modifying the
17 first-half of the sentence, a reading that was clearly not
18 intended by the drafters. With these small changes we can move
19 forward and encourage support from both sides of the dias. I yield
20 back.

21 The Chairman. The gentleman yields back. Other members
22 wishing to speak on the amendment? The gentleman from
23 Massachusetts, Mr. Kennedy, is recognized for five minutes.

24 Mr. Kennedy. Thank you, Mr. Chairman. Move to strike the last

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1 word.

2 Mr. Chairman, I want to thank you for bringing this Bill to
3 a Markup. I'm pleased to say that we engaged in good faith
4 discussions over the past month, and I sincerely appreciate the
5 work on both the Minority and Majority Staff, as well as some
6 outside groups that were working on this issue.

7 We all agree that form contracts containing non-disparaging
8 clauses in their terms of service are simply unacceptable. Just
9 like posing a positive experience, consumers have an undeniable
10 right to voice their honest concerns when they experience fails
11 to meet those expectations.

12 This amendment is a technical addition to insuring the
13 language of the Bill does not limit, impair, or supersede the
14 operation of the Federal Trade Commission. I ask my colleagues
15 to support this amendment and the underlying Bill, and I yield
16 back the balance of my time.

17 The Chairman. The gentleman yields back. Other members
18 wishing to speak on the amendment? Seeing none, the vote occurs
19 on the amendment offered by the gentleman from Texas, Mr. Burgess.
20 All those in favor say aye.

21 [A chorus of ayes]

22 The Chairman. Those opposed say no. The ayes appear to have
23 it, the ayes have it, and the amendment is agreed to. Are there
24 further amendments to the Bill?

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1 Seeing none, the question now occurs on favorably reporting
2 H.R. 5111 as amended to the House. All those in favor shall signify
3 by saying aye.

4 [A chorus of ayes]

5 The Chairman. Those opposed say no. The ayes appear to have
6 it, the ayes have it, and the Bill is favorably reported.

7 The Chair would now call up H.R. 921 as forwarded by the
8 Subcommittee on Health on June 8th, and ask the Clerk to report.

9 [The Bill H.R. 921 follows:]

10

11 *****INSERT 5*****

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1 The Clerk. H.R. 921, to provide protections for certain
2 sports medicine professionals who provide certain medical
3 services in a secondary state.

4 The Chairman. Without objection the first reading of the Bill
5 is dispensed with, and the Bill will be open for amendment at any
6 point. The Chair would recognize Mr. Guthrie for the purpose of
7 offering an amendment in the nature of a substitute, and the Clerk
8 will report the title.

9 [The Amendment offered by Mr. Guthrie follows:]

10

11 *****INSERT 6*****

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1 The Clerk. Amendment in the nature of a substitute to H.R.
2 921 offered by Mr. Guthrie.

3 The Chairman. The amendment will be considered as read. The
4 Staff will distribute the amendment, and the gentleman is
5 recognized for five minutes.

6 Mr. Guthrie. Thank you, Mr. Speaker. I thank the Ranking
7 Member Green for joining me and offering this amendment from the
8 subcommittee.

9 This bipartisan amendment in the nature of a substitute makes
10 several changes that clarify the scope and intent of the Bill,
11 which currently has 180 bipartisan cosponsors. This legislation
12 addresses a small but important issue. When sports medicine
13 professionals travel with their teams to sporting events out of
14 state, they currently may not be covered by their malpractice
15 insurance in providing care to injured athletes at great personal
16 and professional risk.

17 H.R. 921 will remedy this problem by clarifying that sports
18 medicine professionals will be covered by their professional
19 liability insurance during these limited out-of-state
20 situations.

21 I appreciate the hard work of the committee's staffs on both
22 sides of the aisle they put into polishing this Bill over the last
23 few weeks. Specifically, I want to thank John Stone on the Majority
24 side, and Arielle Woronoff on the Minority staff for all their

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1 work done to get us to where we are today. I also expressly want
2 to thank Megan Jackson on my Staff, who spent countless hours into
3 getting the definitions correct to make sure that we define when
4 a home team is playing and when they're playing out-of-state, so
5 we really appreciate that. I also want to thank legislative
6 counsel for their guidance and expertise in drafting this Bill.

7 I want to encourage my colleagues to vote yes on the amendment
8 and support the final passage of this important Bill, and I yield
9 back the balance of time.

10 The Chairman. The gentleman yields back. The gentleman from
11 Texas, Mr. Green.

12 Mr. Green. Mr. Chairman, I ask strike the last word. I want
13 to thank you, Mr. Chairman and join Mr. Guthrie in offering the
14 amendment in the nature of a substitute. The bipartisan amendment
15 makes improvements on H.R. 921, the Sports Medicine Licensure
16 Clarity Act. The underlying legislation will promote the safety
17 of our athletes by insuring that sports teams, physicians,
18 athletic trainers, and other providers are covered by their
19 malpractice insurance when providing care to injured athletes
20 both home and away, and no matter what across state lines.

21 The change clarifies the scope and intent of the Bill, and
22 I urge my colleagues to support the amendment and final passage
23 of the legislation. And if there are no questions, I'll be glad
24 to yield back.

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1 The Chairman. The gentleman yields back. Further discussion
2 on the amendment? Seeing none, the vote occurs on the amendment
3 in the nature of a substitute. All those in favor will say aye.

4 [A chorus of ayes]

5 The Chairman. Those opposed say no. In the opinion of The
6 Chair, the ayes have it, the ayes have it, and the amendment in
7 the nature of a substitute is agreed to.

8 Further amendment to the Bill? Seeing none, the vote occurs
9 on H.R. 921 as amended. All those in favor will say aye.

10 [A chorus of ayes]

11 The Chairman. Those opposed say no. The opinion of the Chair,
12 the ayes have it, the ayes have it, and the Bill as amended is
13 agreed to.

14 The Chair will now call up H.R. 5104 as forwarded by the
15 Subcommittee on Commerce, Manufacturing and Trade on June 9th,
16 and ask the Clerk to report.

17 [The Bill H.R. 5104 follows:]

18

19 *****INSERT 7*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 5104, to prohibit as an unfair and deceptive
2 act or practice in commerce the sale or use of certain software
3 to circumvent control measures used by internet ticket sellers
4 to insure equitable consumer access to tickets for any given
5 event, and for other purposes.

6 The Chairman. And without objection the first reading of the
7 Bill is dispensed with, and the Bill will be open for amendment
8 at any point. Are there any bipartisan amendments to the Bill?
9 Are there any amendments to the Bill? The gentleman from New
10 Jersey, Mr. Pallone has the amendment at the desk.

11 [The Amendment offered by Mr. Pallone follows:]

12

13 *****INSERT 8*****

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1 Mr. Pallone. Yes, this is the trans -- there are two
2 amendments. This one I guess is D.O.1, Pallone D.O.1.

3 The Chairman. And the Clerk will report the title of the
4 amendment.

5 The Clerk. Amendment to H.R. 5104 offered by Mr. Pallone.

6 The Chairman. And the amendment will be considered as read.
7 The Staff will distribute the amendment, and the gentleman from
8 New Jersey is recognized for five minutes in support of his
9 amendment.

10 Mr. Pallone. Thank you, Mr. Chairman.

11 I support the purpose of H.R. 5014, the BOTS Act, and I
12 support the Bill. At the legislative hearing a few weeks ago,
13 Representative Blackburn said that the purpose of this Bill is
14 to keep the marketplace fair, and my amendment would help insure
15 fairness. While I support this Bill, I don't think it goes far
16 enough. H.R. 5245, the BOSS Act which was introduced by
17 Representative Pascrell and discussed at our last legislative
18 hearing, would take a more comprehensive approach to making ticket
19 buying a positive experience for consumers. So the amendment I
20 am offering incorporates portions of the BOSS Act that will
21 increase transparency and increase fairness for consumers.

22 A few weeks ago, the CEO of Ticketmaster, he was the CEO from
23 2010 to 2013, Nathan Hubbard, wrote that he agreed with the need
24 for increased transparency and fairness. In his article he said

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1 and I quote, "A fan's guide to why you're totally screwed, he
2 called on artists and venues to tell us regular people how many
3 tickets are going on sale." So increased transparency does help
4 consumers. My amendment insures that ticket buyers know how many
5 tickets will be available for sale and how they can get those
6 tickets. It insures consumers understand the true demand for
7 tickets. When only 1,000 tickets of 15,000 are available for the
8 general public, those few tickets will inevitably sell out much
9 faster.

10 The recent CEO of Ticketmaster also called on fans to push
11 venues and promoters to stop charging outrageous ticket fees, and
12 my amendment will at least help ticket buyers know the full price
13 of the ticket, including any additional fees before they decide
14 which tickets to buy so fans can avoid losing out on getting
15 tickets because they wasted time trying to buy tickets they
16 couldn't actually afford due to extra fees that put those tickets
17 out of their budget. And this amendment will prevent scalpers from
18 selling tickets they do not actually have possession of, which
19 insures that consumers are not paying for tickets that they never
20 get.

21 I agree that the use of BOTS in the ticketing marketplace
22 is a problem, but it's just one of many problems. And to truly
23 make the ticketing system work better for consumers, I think we
24 must do more, and this amendment takes another step in that

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1 direction. So I would urge my colleagues to support the amendment,
2 and I yield back.

3 The Chairman. The gentleman yields back. The Chair
4 recognizes the gentlelady from Tennessee, Mrs. Blackburn, for
5 five minutes.

6 Mrs. Blackburn. Thank you, Mr. Chairman.

7 What this amendment would end up doing is to subject live
8 entertainment to a type of regulation that almost no other
9 industry faces. It would require them to place proprietary
10 information in a public domain. We have talked about this; we
11 discussed it as we were in our subcommittee.

12 Now what this would do also, these inventory disclosures that
13 Mr. Pallone would like to see, this would help scalpers to do a
14 better job at what they are trying to do. So it will not make a
15 single additional ticket available to a single additional fan.
16 And I think that we need to realize that this amendment would
17 require disclosure of information that really wouldn't be of any
18 use to the average fan because even if they were aware of it, they
19 wouldn't have a context in which to use the information. What they
20 want to do is be able to click on, choose a seat, and complete
21 that purchase and not have the BOTsters get all the tickets before
22 they have the chance.

23 The other thing we have to do is to look at the artist
24 set-asides and what they do with the tickets for their fan clubs.

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1 And fan clubs are generally open to the public, they're free to
2 join. There is nothing wrong with this. Artists often do deals
3 with credit card companies to give privileged access to a certain
4 credit card holder in return for compensation. It is a business
5 decision that allows them to charge less for the tickets overall.
6 It's a good thing for consumers, and they still remain profitable.

7 And what we want to do is to keep our attention as we focus
8 on making certain that we don't hamper the marketplace. And with
9 that, Mr. Chairman, I will yield my time back.

10 The Chairman. The gentlelady yields back. Other members
11 wishing to -- the gentleman from Pennsylvania, Mr. Doyle.

12 Mr. Doyle. Thank you, Mr. Chairman. Mr. Chairman, I move to
13 strike the last word.

14 First off, I'd like to ask unanimous consent to place two
15 letters from public interest groups supporting comprehensive
16 reforms that are included in the amendment offered by Ranking
17 Member Pallone.

18 The Chairman. Without objection.

19 Mr. Doyle. Thank you. We need to take more substantial steps
20 to bring transparency and accountability to the online ticket
21 sales market. The BOSS Act offered by my friend, Mr. Pascrell,
22 did just that, and I encourage my colleagues to support the
23 amendment offered by our Ranking Member which includes many of
24 the improvements from the BOSS Act.

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1 And, Mr. Chairman, with that, I'll yield back.

2 The Chairman. The gentleman yields back. Other members
3 wishing to speak on the amendment? The gentlelady from Illinois,
4 Ms. Schakowsky, is recognized for five minutes.

5 Ms. Schakowsky. I am speaking in favor of the Ranking
6 Member's amendment. It would include the BOSS Act transparency
7 provisions on the price and availability of tickets creating a
8 better overall environment for ticket buyers. I think both the
9 BOTS and the BOSS Act merit consideration. We should be looking
10 at the online ticket marketplace overall and figuring out how to
11 make it work best for consumers. I think the addition of the BOSS
12 Act which was first introduced by Congressman Pascrell to create
13 more transparency in the ticket market, it was -- it should be
14 added to the legislation that we're doing today to make a really
15 good Bill for consumers. And I yield back.

16 The Chairman. The gentlelady yields back. Other members
17 wishing to speak? Seeing none the vote occurs on the amendment
18 offered by the gentleman from New Jersey, Mr. Pallone. All those
19 in favor will say aye.

20 [A chorus of ayes]

21 The Chairman. Those opposed say no.

22 [A chorus of nos]

23 The Chairman. The nos have it, the nos have it, and the
24 amendment is not agreed to.

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1 Further amendments to the Bill? You want to go? Gentleman
2 from New Jersey has an amendment at the desk.

3 Mr. Pallone. This one is D.O 2.

4 The Chairman. D.O 2 or D.O 1? Is it 2?

5 Mr. Pallone. This is D.O.2.

6 [The Amendment offered by Mr. Pallone follows:]

7

8 *****INSERT 9*****

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1 The Chairman. The Clerk will report the title of the
2 amendment.

3 The Clerk. Amendment to H.R. 5104 offered by Mr. Pallone.

4 The Chairman. The amendment will be considered as read. The
5 Staff will distribute the amendment, and the gentleman is
6 recognized for five minutes in support of his amendment.

7 Mr. Pallone. Thank you, Mr. Chairman.

8 Again, I support the purpose of the BOTS Act, but this Bill
9 does not do enough to address the problems consumers face in the
10 online ticket marketplace. Since the committee is not taking the
11 additional steps laid out in my previous amendment to help
12 consumers, I'm offering an amendment that would direct the
13 Government Accountability Office to conduct a study of the ticket
14 market to determine the current state of play. In particular, the
15 study would determine who is buying tickets from primary sellers,
16 and how many tickets are resold later, the effect of
17 nontransferable tickets on consumers, and the extent to which BOTS
18 are actually used.

19 While the New York Attorney General report was extremely
20 helpful in identifying many of the problems in the ticketing
21 space, a GAO report could look at the national problems, as well
22 as look at best practices internationally. It also could discuss
23 the pros and cons of potential solutions, such as the suggestion
24 to prevent speculative ticketing selling, and that tickets become

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1 paperless.

2 So my amendment does not change the purpose of the BOTS Act,
3 and it does not make any changes to the current online ticket
4 marketplace. It would only insure that we have some helpful
5 information to help us better consider these issues in the future.
6 And so I hope my colleagues will support my amendment, and I yield
7 back, Mr. Chairman.

8 The Chairman. Are there other members wishing to speak on
9 the amendment? The gentlelady from Tennessee.

10 Mrs. Blackburn. Yes, a couple of things I want to mention
11 about a proposed study. I would want my colleagues to know that
12 you have Senators Schumer, Moran, Blumenthal, and Fischer who are
13 filing a Bill today in the Senate. It doesn't have a study in it.
14 It mirrors the product that we are bringing forward to you today.

15 Now one of the reasons we don't need the GAO to take their
16 time and resources to do a study is because we've already got these
17 from the states. I've got two in my hands, one from New York, and
18 one from Connecticut. The reason we are looking at addressing this
19 on the federal level is because the states have looked at this.
20 And I think that a study would be an unnecessary expense. These
21 studies primarily, they're not performed by the GAO. They're done
22 through the state agencies, and they have been done. We have had
23 those. I think that to turn around and to do this again is just
24 to delay this process.

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1 BOTS are unique an issue because they can't be always handled
2 at a state level. They are interstate in nature. The state studies
3 have shown that. They've already decided that, and that's why we
4 have our Bill. The Senate is putting their companion legislation
5 in today. It is bipartisan. The BOTS Act is a bipartisan Bill,
6 and it seeks to address a narrowly defined interstate problem and
7 regulation of the primary ticketing market, or any of these
8 additional studies is something that we really don't need to spend
9 the time and effort into.

10 With that, Mr. Chairman, I will just yield my time back.

11 The Chairman. The gentlelady yields back. The gentleman from
12 Pennsylvania, Mr. Doyle, is recognized for five minutes.

13 Mr. Doyle. Thank you, Mr. Chairman. I just want to add my
14 voice to support the amendment of the gentleman, and to ask
15 unanimous consent to place a letter from the National Consumers
16 League in the record. Mr. Chairman?

17 The Chairman. If the gentleman might withdraw his amendment,
18 if maybe I can work on a letter asking for a study but not make
19 it part of the Bill, would the gentleman withdraw the amendment?

20 Mr. Doyle. I yield back to Mr. Pallone.

21 The Chairman. I'm sorry. I was in a different --

22 Mr. Doyle. I ask unanimous consent for the National Consumer

23 --

24 The Chairman. Without objection.

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1 Mr. Doyle. Thank you. And I'll yield to Mr. Pallone.

2 Mr. Pallone. Can you just repeat that again?

3 The Chairman. I'm just asking, I do not support adding the
4 amendment to the Bill requesting a study, but I will -- if the
5 gentleman would withdraw the amendment, I will work on a letter
6 requesting a study from GAO, but not as part of the legislation
7 itself.

8 Mr. Pallone. Oh, that's fine.

9 The Chairman. If the gentleman will withdraw his amendment.

10 Mr. Pallone. Sure, I'll withdraw the amendment. Thanks.

11 The Chairman. With that understanding, the gentleman
12 withdraws his amendment. Are there further amendments to the Bill?
13 Seeing none -- I'm sorry, the gentlelady from Illinois has
14 amendment at the desk.

15 [The Amendment offered by Ms. Schakowsky follows:]

16

17 *****INSERT 10*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Chairman. And the Clerk will report the title of the
2 amendment.

3 The Clerk. Amendment to H.R. 5104 offered by Ms. Schakowsky.

4 The Chairman. And without objection the amendment will be
5 considered as read. The Staff will distribute the amendment, and
6 the gentlelady is recognized for five minutes in support of her
7 amendment.

8 Ms. Schakowsky. Thank you, Mr. Chairman.

9 My amendment strengthens the BOTS Act by restoring the civil
10 action provision included when this bill was introduced with
11 bipartisan support last year and again when this bill was
12 reintroduced in April. The civil action provision was not included
13 in the substitute amendment in subcommittee which is unfortunate
14 because it gave the bill real teeth.

15 As Vice Chair Blackburn said in April, "The BOTS Act will
16 allow FTC enforcement and a private right of action to be brought
17 against proven online scalpers. It is time to end this
18 anti-consumer tactics and level the online ticket playing field
19 for fans of live entertainment," she continued.

20 If we want to make real progress in stopping BOTS we need
21 both FTC enforcement and civil action. The FTC has limited
22 resources to enforce this bill all on its own. The original version
23 with both FTC enforcement and civil action had bipartisan support,
24 as I said, from 17 Representatives, including several members of

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1 this committee, as well as the support of the Recording Academy,
2 Pandora, Ticketfly, and LiveNation Entertainment.

3 I urge my colleagues to make this bill stronger and restore
4 the original civil action language. And with that, I yield back.

5 Mr. Pallone. Would the gentlewoman yield?

6 Ms. Schakowsky. Oh, I would yield to the Ranking Member, yes.

7 Mr. Pallone. I just want to support Ms. Schakowsky's
8 amendment. Mrs. Blackburn, as we know, introduced two different
9 versions of this bill. Both versions were bipartisan, and both
10 included a private right of action. And that provision would have
11 allowed consumers who are harmed because someone's use of BOTS
12 to bring a lawsuit against that person in court. So this amendment
13 empowers consumers to protect themselves and seek redress when
14 they're harmed, and this provision has received bipartisan
15 support in the past, and I hope my colleagues will support it now.

16 I yield back.

17 Ms. Schakowsky. And I yield back.

18 The Chairman. The Chair would recognize the gentlelady from
19 Tennessee, Mrs. Blackburn, for five minutes.

20 Mrs. Blackburn. Thank you. And, Mr. Chairman, they are
21 correct. The original BOTS did have a private right of action in
22 it, and that is something that was truly a point of discussion.
23 The reality is, as I have learned through this process, ticketing
24 agents already have access to a private right of action. They have

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1 that private right of action.

2 I will also tell you that the Senate version that Senators
3 Schumer, Moran, Blumenthal, and Fischer are introducing in the
4 Senate does not include a private right of action because they
5 want to actually pass a law that helps consumers, and they know
6 that if a private right of action is included that we're not going
7 to get this signed into law.

8 So we all know that the ticket agents are concerned about
9 the BOT issue. We know that BOTS violate the terms and conditions
10 of the ticketing website, and a BOTSter has violated the terms
11 of a contract into which he or she has entered when they utilize
12 the BOT software. So through that, the ticketing agents say they
13 have a private right of action. Ticketmaster has actually
14 successfully sued some scalpers who used BOTS. They've done it
15 several occasions, they have done it under state law. They
16 successfully sued RMG Technologies, a BOT manufacturer in '07,
17 and in Ticketmaster versus Salome and 13 others, they sued
18 operators of a BOT network in 2012. So when we introduced H.R.
19 5104 we recognized that creating a new federal private right of
20 action would bring unnecessary controversy to the bill creating
21 new federal torts which is something that is unnecessary.

22 So with that, yes, the private right of action was moved.
23 The Senate has chosen to keep it out of their bill. We should do
24 likewise. And with that, Mr. Chairman, I yield back.

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1 Ms. Schakowsky. Would the gentlelady yield for just a
2 sentence or two?

3 Mrs. Blackburn. Sure.

4 Ms. Schakowsky. Thank you. You're right that ticket agents
5 would have a state private right of action. Individuals would not,
6 and so this amendment would include individuals in having that.
7 And thank you for yielding.

8 Mrs. Blackburn. Indeed.

9 The Chairman. The gentlelady yields back. Other members
10 wishing to speak on the amendment? Seeing none, the vote occurs
11 on the amendment offered by the gentlelady from Illinois. All
12 those in favor will say aye.

13 [A chorus of ayes]

14 The Chairman. Those opposed say no.

15 [A chorus of nos]

16 The Chairman. Opinion of the Chair, the nos have it.

17 Ms. Schakowsky. I'd like a --

18 The Chairman. Roll call vote is requested. The Clerk will
19 call the roll.

20 The Clerk. Mr. Barton.

21 Mr. Barton. No.

22 The Clerk. Mr. Barton votes no.

23 Mr. Whitfield. Mr. Shimkus.

24 Mr. Shimkus. No.

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1 The Clerk. Mr. Shimkus votes no.

2 Mr. Pitts.

3 Mr. Pitts No.

4 The Clerk. Mr. Pitts votes no.

5 Mr. Walden.

6 Mr. Walden. No.

7 The Clerk. Mr. Walden votes no.

8 Mr. Murphy.

9 Mr. Murphy No.

10 The Clerk. Mr. Murphy votes no.

11 Mr. Burgess.

12 Mr. Burgess. No.

13 The Clerk. Mr. Burgess votes no.

14 Mrs. Blackburn.

15 Mrs. Blackburn. No.

16 The Clerk. Mrs. Blackburn votes no.

17 Mr. Scalise.

18 Mr. Scalise. No.

19 The Clerk. Mr. Scalise votes no.

20 Mr. Latta.

21 Mr. Latta. No.

22 The Clerk. Mr. Latta votes no.

23 Mrs. McMorris Rodgers.

24 Mrs. McMorris Rodgers. No.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. Mrs. McMorris Rogers votes no.

2 Mr. Harper.

3 Mr. Harper. No.

4 The Clerk. Mr. Harper votes no.

5 Mr. Lance.

6 Mr. Lance. No.

7 The Clerk. Mr. Lance votes no.

8 Mr. Guthrie.

9 Mr. Guthrie. No.

10 The Clerk. Mr. Guthrie votes no.

11 Mr. Olson.

12 Mr. Olson. No.

13 The Clerk. Mr. Olson votes no.

14 Mr. McKinley.

15 Mr. McKinley. No.

16 The Clerk. Mr. McKinley votes no.

17 Mr. Pompeo.

18 [No response.]

19 The Clerk. Mr. Kinzinger.

20 Mr. Kinzinger. No.

21 The Clerk. Mr. Kinzinger votes no.

22 Mr. Griffith.

23 Mr. Griffith. No.

24 The Clerk. Mr. Griffith votes no.

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1 Mr. Bilirakis.

2 Mr. Bilirakis. No.

3 The Clerk. Mr. Bilirakis votes no.

4 Mr. Johnson.

5 Mr. Johnson. No.

6 The Clerk. Mr. Johnson votes no.

7 Mr. Long.

8 Mr. Long. No.

9 The Clerk. Mr. Long votes no.

10 Mrs. Ellmers.

11 Mrs. Ellmers. No.

12 The Clerk. Mrs. Ellmers votes no.

13 Mr. Bucshon.

14 Mr. Bucshon. No.

15 The Clerk. Mr. Bucshon votes no.

16 Mr. Flores.

17 Mr. Flores. No.

18 The Clerk. Mr. Flores votes no.

19 Mrs. Brooks.

20 Mrs. Brooks. No.

21 The Clerk. Mrs. Brooks votes no.

22 Mr. Mullin.

23 Mr. Mullin. No.

24 The Clerk. Mr. Mullin votes no.

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1 Mr. Hudson.

2 Mr. Hudson. No.

3 The Clerk. Mr. Hudson votes no.

4 Mr. Collins.

5 Mr. Collins. No.

6 The Clerk. Mr. Collins votes no.

7 Mr. Cramer.

8 Mr. Cramer. No.

9 The Clerk. Mr. Cramer votes no.

10 Mr. Pallone.

11 Mr. Pallone. Aye.

12 The Clerk. Mr. Pallone votes aye.

13 Mr. Rush.

14 Mr. Rush. Aye.

15 The Clerk. Mr. Rush votes aye.

16 Ms. Eshoo.

17 Ms. Eshoo. Aye.

18 The Clerk. Ms. Eshoo votes aye.

19 Mr. Engel.

20 [No response.]

21 The Clerk. Mr. Green.

22 Mr. Green. Aye.

23 The Clerk. Mr. Green votes aye.

24 Ms. DeGette.

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1 Ms. DeGette. Aye.

2 The Clerk. Ms. DeGette votes aye.

3 Mrs. Capps.

4 Mrs. Capps. Aye.

5 The Clerk. Mrs. Capps votes aye.

6 Mr. Doyle.

7 Mr. Doyle. Aye.

8 The Clerk. Mr. Doyle votes aye.

9 Ms. Schakowsky.

10 Ms. Schakowsky. Aye.

11 The Clerk. Ms. Schakowsky votes aye.

12 Mr. Butterfield.

13 Mr. Butterfield. Aye.

14 The Clerk. Mr. Butterfield votes aye.

15 Ms. Matsui.

16 Ms. Matsui. Aye.

17 The Clerk. Ms. Matsui votes aye.

18 Ms. Castor.

19 Ms. Castor. Aye.

20 The Clerk. Ms. Castor votes aye.

21 Mr. Sarbanes.

22 Mr. Sarbanes. Aye.

23 The Clerk. Mr. Sarbanes votes aye.

24 Mr. McNerney.

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1 Mr. McNerney. Aye.

2 The Clerk. Mr. McNerney votes aye.

3 Mr. Welch.

4 Mr. Welch. Aye.

5 The Clerk. Mr. Welch votes aye.

6 Mr. Lujan.

7 Mr. Lujan. Aye.

8 The Clerk. Mr. Lujan votes aye.

9 Mr. Tonko.

10 Mr. Tonko. Aye.

11 The Clerk. Mr. Tonko votes aye.

12 Mr. Yarmuth.

13 Mr. Yarmuth. Aye.

14 The Clerk. Mr. Yarmuth votes aye.

15 Ms. Clarke.

16 Ms. Clarke. Aye.

17 The Clerk. Ms. Clarke votes aye.

18 Mr. Loeb sack.

19 Mr. Loeb sack. Aye.

20 The Clerk. Mr. Loeb sack votes aye.

21 Mr. Schrader.

22 Mr. Schrader. Aye.

23 The Clerk. Mr. Schrader votes aye.

24 Mr. Kennedy.

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1 Mr. Kennedy. Aye.

2 The Clerk. Mr. Kennedy votes aye.

3 Mr. Cardenas.

4 Mr. Cardenas. Aye.

5 The Clerk. Mr. Cardenas votes aye.

6 Chairman Upton.

7 Chairman Upton. Votes no.

8 The Clerk. Chairman Upton votes no.

9 The Chairman. Others members wishing to cast a vote or change
10 a vote? Seeing none, the Clerk will report the tally.

11 The Clerk. Mr. Chairman, on that vote there were 22 ayes and
12 29 nos.

13 The Chairman. Twenty-two ayes, 29 nos, the amendment is not
14 agreed to.

15 Are there further amendments to the bill? Seeing none, the
16 question now occurs on favorably reporting H.R. 5104 to the House.
17 All those in favor shall signify by saying aye.

18 [A chorus of ayes]

19 The Chairman. Those opposed say no. Opinion of the Chair,
20 the ayes have it, the ayes have it, and the bill is favorably
21 reported.

22 The Chair would now call up H.R. 670 and ask the Clerk to
23 report.

24 [The Bill H.R. 670 follows:]

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1

2

*****INSERT 11*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 670 to amend Title 29 of the Social Security
2 Act to extend the Medicaid rules regarding supplemental needs
3 trust for Medicaid beneficiaries to trusts established by those
4 beneficiaries and for other purposes.

5 The Chairman. And without objection the first reading of the
6 bill is dispensed with, and the bill will be open for amendment
7 at any point.

8 The Chair would recognize Mr. Lance for the purpose of
9 offering an amendment in the nature of a substitute. And the Clerk
10 will report the title of the amendment.

11 [The Amendment offered by Mr. Lance follows:]

12

13 *****INSERT 12*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. Amendment in the nature of a substitute to H.R.
2 670 offered by Mr. Lance.

3 The Chairman. And the amendment will be considered as read.
4 The Staff will distribute the amendment, and the gentleman from
5 New Jersey is recognized for five minutes in support of his
6 amendment.

7 Mr. Lance. Thank you, Mr. Chairman. I move to strike the last
8 word.

9 Thank you for holding this important markup on this issue.
10 H.R. 670, the Special Needs Trust Fairness Act of 2015 is a
11 targeted improvement to the Medicaid Program. The amendment in
12 the nature of a substitute builds on the underlying bill's
13 commonsense approach. The amendment adds a targeted new benefit
14 for mothers of newborns in requiring State Medicaid Programs to
15 cover tobacco cessation services during the first year of the
16 newborn's life. Under current law, State Medicaid Programs are
17 required to cover cessation services for pregnant women. The
18 policy would extend this to mothers of newborns helping more women
19 make healthy choices, improving their health and the health of
20 their child.

21 This policy was included in the bill that I had sponsored
22 5717, the Medicaid Data and Benefit Improvement Act, and improving
23 access to tobacco cessation services is a policy aim that enjoys
24 wide bipartisan support.

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1 The Centers for Medicare and Medicaid Services has said that
2 cigarette smoking is one of the greatest drivers of adverse health
3 outcomes and costs for state Medicaid programs. By investing in
4 comprehensive tobacco cessation programs, CMS notes that states
5 have reduced smoking rates and health care costs, and have
6 improved health outcomes. In fact, CMS' review of available
7 literature has led the agency to conclude that tobacco treatment
8 is one of the most cost-effective preventative services with as
9 much as a two to three dollar return on every dollar invested.

10 Finally, to offset the increased mandatory outlays from H.R.
11 670, the amendment in the nature of a substitute also includes
12 a policy that would prohibit federal financial participation for
13 drugs used for cosmetic purposes or hair growth except when
14 medically necessary with savings placed in the Medicaid
15 Improvement Fund.

16 I urge my colleagues to adopt this amendment and support the
17 Special Needs Trust Fairness Act. And, Mr. Chairman, I yield back
18 the balance of my time.

19 The Chairman. If the gentleman would just yield for a second.

20 Mr. Lance. Sure.

21 The Chairman. I just want to say that I met with a number
22 of my constituents a couple of weeks ago who were up on the Hill
23 pushing for this legislation, and particularly for families that
24 have a disabled member, I think this is really important. And it

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1 goes along with what we ought to be doing, particularly when the
2 parents or guardians are no longer there. And it's a good
3 bipartisan bill, and I look forward to getting it done on the House
4 floor.

5 Mr. Lance. Thank you, Mr. Chairman.

6 The Chairman. So appreciate the work. Other members wishing
7 to speak on the amendment in the nature of a substitute. Gentleman
8 from New Jersey, Mr. Pallone.

9 Mr. Pallone. Thank you, Mr. Chairman.

10 I strongly support this bipartisan legislation, H.R. 670,
11 the Special Needs Trust Fairness Act. The legislation which I have
12 championed for multiple Congresses now with my Republican
13 colleague, Mr. Glenn Thompson, would allow individuals with
14 disabilities to set up Special Needs Trusts for themselves without
15 a court petition. A Special Needs Trust is a special kind of trust
16 that is designed to provide support for certain expenses for
17 disabled individuals to supplement Medicaid benefits.

18 Currently, these types of trusts generally must be
19 established by parents, grandparents, legal guardians, or a court
20 on behalf of the disabled individual, and those individuals can
21 only set up a Special Needs Trust for themselves after petitioning
22 a court. Oftentimes, this process can take several months and can
23 incur significant legal fees for the disabled individual in the
24 process. And I just don't think that's right; individuals with

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1 disabilities can and should have the ability to set up a Special
2 Needs Trust for themselves, and this legislation fixes that basic
3 inequity.

4 Unfortunately, the legislation before us today is amended
5 by an additional policy that has not been considered through the
6 regular order of the committee, and I want to be clear that I have
7 significant concerns about circumventing our legislative process
8 in this way. Moreover, because H.R. 670 as originally drafted has
9 already passed the Senate, amending this bill further will force
10 reconsideration by the Senate before it can be signed into law.

11 However, with all that, I do -- I don't like the process,
12 obviously, but I believe that H.R. 670 must move forward, and for
13 that reason, I will vote in favor of the bill, and urge my
14 colleagues to vote for it as amended.

15 I yield back.

16 The Chairman. The gentleman yields back. Are there other
17 members wishing to speak on the amendment in the nature of a
18 substitute? Seeing none, the vote occurs on the amendment in the
19 nature of a substitute. All those in favor will signify by saying
20 aye.

21 [A chorus of ayes.]

22 The Chairman. Those opposed say no. The ayes have it, the
23 amendment in the nature of a substitute is agreed to.

24 Are there further amendments to the bill? Seeing none, the

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1 vote occurs on H.R. 670 as amended. All those in favor will say
2 aye.

3 [A chorus of ayes.]

4 The Chairman. Those opposed say no. The opinion of the Chair,
5 the ayes have it, and the bill as amended is agreed to.

6 The Chair will now call up H.R. 5092 and ask the Clerk to
7 report.

8 [The Bill H.R. 5092 follows:]

9

10 *****INSERT 13*****

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1 The Clerk. H.R. 5092, to make exclusive the authority of the
2 federal government to regulate the labeling of products made in
3 the United States and introduced in interstate or foreign
4 commerce, and for other purposes.

5 The Chairman. And without objection the first reading of the
6 bill is dispensed with, and the bill will be open for amendment
7 at any point. Are there any bipartisan amendments to the bill?
8 Are there any amendments to the bill? The gentleman from
9 Massachusetts might have an amendment at the desk. The Clerk will
10 report the title of the amendment.

11 Mr. Kennedy. It's Ken M.A. 33.

12 [The Amendment offered by Mr. Kennedy follows:]

13

14 *****INSERT 14*****

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1 The Chairman. Number 33?

2 The Clerk. Amendment to H.R. 5092 offered by Mr. Kennedy.

3 The Chairman. The amendment will be considered as read. The
4 Staff will distribute the amendment, and the gentleman from
5 Massachusetts is recognized for five minutes in support of his
6 amendment.

7 Mr. Kennedy. Thank you, Mr. Chairman.

8 Last month at the Commerce Manufacture and Trade
9 Subcommittee Markup, I offered this same amendment as a compromise
10 to the issues this bill is attempting to address, providing
11 certainty for the business community while insuring that consumer
12 protections remain in place. Last month, I offered and withdrew
13 this amendment under the prospect of the two sides coming together
14 to agree on language that accomplishes both of these goals. I'm
15 pleased to say we had several positive discussions following the
16 subcommittee markup. Unfortunately, I'm disappointed that we were
17 unable to come to an agreement in writing.

18 This legislation seeks to accomplish a worthy goal
19 establishing a singular national standard for what it means to
20 be Made in America. I understand and support that goal. I've heard
21 from manufacturers in my own home state that seek to meet the high
22 standards of manufacturing goods here in the United States, and
23 deservingly should be able to proudly display the Made in America
24 label on their products. However, as currently written the bill

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1 places that goal of business certainty at the expense of
2 consumers. The bill completely preempts any state laws relating
3 to Made in the USA manufacturing claims. This includes any state
4 law providing consumer protection provisions such as state
5 remedies and private rights of action.

6 My amendment balances these interests in three ways. First,
7 it establishes a singular national standard for Made in America
8 labeling requirements for manufactured goods. State would be
9 permitted to pass their own laws so long as the standard is
10 identical to that of the FTC. Second, it would keep state authority
11 and common law consumer protections in place. And third, it
12 provides State Attorneys General the authority to enforce the FTC
13 standard. None of these provisions are groundbreaking, nor are
14 they a dramatic departure from some of the bipartisan policies
15 both sides are supporting today in the other legislation before
16 this committee.

17 As I said last month, it has been my understanding that the
18 sole purpose of this legislation is to create one standard for
19 Made in America manufacturing with which businesses need to
20 comply. This Made in the USA label affixed to products is a
21 valuable tool and a mark of distinction. Businesses meeting the
22 high standard of Made in the USA deserve to proudly display that
23 label on their products, but that mark of distinction cannot come
24 at the expense of consumer protection, and these are not mutually

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1 exclusive goals.

2 I firmly believe that this amendment represents a
3 compromised balance of both the interests of the Majority and the
4 Minority, the business community, and consumer protection
5 advocates. I urge adoption of this amendment, and I yield back
6 the balance of my time.

7 The Chairman. Gentleman yields back his time. Other members
8 wishing to speak? Mr. Harper is recognized for five minutes.

9 Mr. Harper. Thank you, Mr. Chairman. And I certainly
10 appreciate the Congressman's desire to come to an agreement on
11 this, and I was pleased that we've been able to have this
12 discussion.

13 The purpose of this legislation is to establish a single
14 national standard. This is the same text as S. 1518 which passed
15 the Senate Commerce Committee by voice vote, and I'm encouraged
16 that there have been efforts to find compromise prior to this Full
17 Committee Markup. And I do remain hopeful that those conversations
18 can continue after we report out of committee today.

19 Any deal struck at this late date should be the ones that
20 can pass both the House and the Senate. We may be willing to
21 consider some additional state roles, but can only do so in the
22 context of everyone at the table reaching a final agreement that
23 would become law. Absent such an agreement, I cannot support
24 changes to the bill at this time. However, I cannot support a

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1 blanket authorization for 50 Attorneys General to pursue
2 companies trying to comply in good faith with the FTC's
3 guidelines.

4 Companies that manufacture in the United States should be
5 encouraged to label their products as Made in the USA. They
6 shouldn't be sacrificial lambs for the political agendas of state
7 bureaucrats.

8 I believe that a welcome mat for State AGs to penalize the
9 job creators we are trying to help is counter to the intent of
10 this underlying legislation. So this is really, I think, an
11 unnecessary departure from the bill that passed the Senate
12 Commerce Committee by voice vote on a bipartisan basis. I also
13 note that the legislation is a good complement to the FTC Process
14 and Transparency Reform Act which we also voted on today.

15 My bill preempts a set of rules that are currently so
16 difficult to comply with that they might as well be a ban on Made
17 in USA labels. Similarly, the Transparency Reform legislation
18 helps clarify some ambiguity in the kinds of activity that are
19 prohibited under the FTC Act. Together these bills will help U.S.
20 manufacturers keep jobs here, so I certainly would encourage
21 everyone to support the underlying bill, but to vote no on this
22 amendment. And with that, I yield back.

23 The Chairman. The gentleman yields back. The Chair
24 recognizes the gentleman from New Jersey, Mr. Pallone, for five

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1 minutes.

2 Mr. Pallone. Thank you, Mr. Chairman.

3 I'm speaking in support of Mr. Kennedy's amendment. I'm
4 sympathetic to the problem for manufacturers that is caused by
5 multiple standards for using the Made in America label as part
6 of marketing practices, but in my opinion, Mr. Kennedy's amendment
7 strikes the necessary balance. Like the underlying bill, the
8 amendment would ease burdens on manufacturers by creating a single
9 national standard for Made in America advertising, but the
10 amendment would also allow Californians to continue to enforce
11 the national standard as it currently enforces the state standard.
12 It would also allow other State Attorney Generals to enforce the
13 law to protect consumers from true deceptive advertising.

14 I've heard from companies who have tried to comply with the
15 different federal and state standards by creating a different
16 packaging, one type without the Made in America label for sales
17 within a single state, and another type of packing with the label
18 for the rest of the country, but those manufacturers often sell
19 to distributors and retailers, not directly to consumers. In that
20 process, they lose control of where their products go.

21 In at least one situation I heard about the distributor
22 redirected products that were meant for other locations into
23 California, which has a standard for Made in America advertising
24 that is different from the federal standard. California's law

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1 allows enforcement by the California Attorney General, and allows
2 citizens who have been misled by noncompliant advertising to bring
3 cases against the manufacturers. The broad preemption of the
4 underlying bill would stop these avenues of recourse.

5 Under Mr. Kennedy's amendment, consumers who were deceived
6 by noncompliant advertising would still have recourse, but
7 companies acting in good faith won't be subjected to undue
8 burdens. So while I'm generally wary of preemption, it may be
9 merited in this case.

10 So I support this amendment, and I urge my colleagues to
11 support its adoption. I yield back.

12 The Chairman. Gentleman yields back. Other members wishing
13 to speak on the amendment? Seeing -- the gentlelady from Illinois.

14 Ms. Schakowsky. Thank you. I just want to support the Kennedy
15 amendment to allow for state enforcement of the federal standard
16 for the Made in America label. H.R. 5092 preempts state standards
17 for Made in America so there is a single nationwide standard.

18 I understand the desire for a consistent standard among
19 businesses operating in multiple states, but we should not
20 undermine state enforcement if we want the standard to be
21 effective. The FTC has limited resources to insure compliance with
22 its standard. If a state like California wants to enact laws to
23 help enforce the standard, why wouldn't we want to allow that?
24 The Kennedy amendment lets State Attorneys General enforce the

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1 federal standard, and it allows states to adopt the federal
2 standard and enact their own enforcement laws. If we're all for
3 this Made in America label, then I urge adoption of this amendment.
4 I do not believe the bill should advance without it, and I yield
5 back.

6 The Chairman. Gentlelady yields back. Other members wishing
7 to speak on the amendment? Seeing none, the vote occurs on the
8 Kennedy amendment. Those in favor will say aye.

9 [A chorus of ayes.]

10 The Chairman. Those opposed say no.

11 [A chorus of nos.]

12 The Chairman. Opinion of the Chair -- roll call is asked for.
13 The Clerk will call the tally.

14 The Clerk. Mr. Barton.

15 Mr. Barton. No.

16 The Clerk. Mr. Barton votes no.

17 Mr. Whitfield.

18 Mr. Whitfield. No.

19 The Clerk. Mr. Whitfield votes no.

20 Mr. Shimkus.

21 Mr. Shimkus. No.

22 The Clerk. Mr. Shimkus votes no.

23 Mr. Pitts.

24 Mr. Pitts. No.

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1 The Clerk. Mr. Pitts votes no.

2 Mr. Walden.

3 Mr. Walden. No.

4 The Clerk. Mr. Walden votes no.

5 Mr. Murphy.

6 Mr. Murphy. No.

7 The Clerk. Mr. Murphy votes no.

8 Mr. Burgess.

9 Mr. Burgess. No.

10 The Clerk. Mr. Burgess votes no.

11 Mrs. Blackburn.

12 Mrs. Blackburn. No.

13 The Clerk. Mrs. Blackburn votes no.

14 Mr. Scalise.

15 Mr. Scalise. No.

16 The Clerk. Mr. Scalise votes no.

17 Mr. Latta.

18 Mr. Latta. No.

19 The Clerk. Mr. Latta votes no.

20 Mrs. McMorris Rodgers.

21 [No response.]

22 The Clerk. Mr. Harper.

23 Mr. Harper. No.

24 The Clerk. Mr. Harper votes no.

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1 Mr. Lance.

2 Mr. Lance. No.

3 The Clerk. Mr. Lance votes no.

4 Mr. Guthrie.

5 Mr. Guthrie. No.

6 The Clerk. Mr. Guthrie votes no.

7 Mr. Olson.

8 Mr. Olson. No.

9 The Clerk. Mr. Olson votes no.

10 Mr. McKinley.

11 Mr. McKinley. No.

12 The Clerk. Mr. McKinley votes no.

13 Mr. Pompeo.

14 [No response.]

15 The Clerk. Mr. Kinzinger.

16 Mr. Kinzinger. No.

17 The Clerk. Mr. Kinzinger votes no.

18 Mr. Griffith.

19 Mr. Griffith. No.

20 The Clerk. Mr. Griffith votes no.

21 Mr. Bilirakis.

22 Mr. Bilirakis. No.

23 The Clerk. Mr. Bilirakis votes no.

24 Mr. Johnson.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 [No response.]

2 The Clerk. Mr. Long.

3 Mr. Long. No.

4 The Clerk. Mr. Long votes no.

5 Mrs. Ellmers.

6 Mrs. Ellmers. No.

7 The Clerk. Mrs. Ellmers votes no.

8 Mr. Bucshon.

9 Mr. Bucshon. No.

10 The Clerk. Mr. Bucshon votes no.

11 Mr. Flores.

12 Mr. Flores. No.

13 The Clerk. Mr. Flores votes no.

14 Mrs. Brooks.

15 Mrs. Brooks. No.

16 The Clerk. Mrs. Brooks votes no.

17 Mr. Mullin.

18 Mr. Mullin. No.

19 The Clerk. Mr. Mullin votes no.

20 Mr. Hudson.

21 Mr. Hudson. No.

22 The Clerk. Mr. Hudson votes no.

23 Mr. Collins.

24 Mr. Collins. No.

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1 The Clerk. Mr. Collins votes no.

2 Mr. Cramer.

3 Mr. Cramer. No.

4 The Clerk. Mr. Cramer votes no.

5 Mr. Pallone.

6 Mr. Pallone. Aye.

7 The Clerk. Mr. Pallone votes aye.

8 Mr. Rush.

9 Mr. Rush. Aye.

10 The Clerk. Mr. Rush votes aye.

11 Ms. Eshoo.

12 Ms. Eshoo. Aye.

13 The Clerk. Ms. Eshoo votes aye.

14 Mr. Engel.

15 [No response.]

16 The Clerk. Mr. Green.

17 Mr. Green. Aye.

18 The Clerk. Mr. Green votes aye.

19 Ms. DeGette.

20 Ms. DeGette. Aye.

21 The Clerk. Ms. DeGette votes aye.

22 Mrs. Capps.

23 Mrs. Capps. Aye.

24 The Clerk. Mrs. Capps votes aye.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Doyle.

2 Mr. Doyle. Aye.

3 The Clerk. Mr. Doyle votes aye.

4 Ms. Schakowsky.

5 Ms. Schakowsky. Aye.

6 The Clerk. Ms. Schakowsky votes aye.

7 Mr. Butterfield.

8 Mr. Butterfield. Aye.

9 The Clerk. Mr. Butterfield votes aye.

10 Ms. Matsui.

11 Ms. Matsui. Aye.

12 The Clerk. Ms. Matsui votes aye.

13 Ms. Castor.

14 Ms. Castor. Aye.

15 The Clerk. Ms. Castor votes aye.

16 Mr. Sarbanes.

17 Mr. Sarbanes. Aye.

18 The Clerk. Mr. Sarbanes votes aye.

19 Mr. McNerney.

20 Mr. McNerney. Aye.

21 The Clerk. Mr. McNerney votes aye.

22 Mr. Welch.

23 Mr. Welch. Aye.

24 The Clerk. Mr. Welch votes aye.

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1 Mr. Lujan.

2 Mr. Lujan. Aye.

3 The Clerk. Mr. Lujan votes aye.

4 Mr. Tonko.

5 Mr. Tonko. Aye.

6 The Clerk. Mr. Tonko votes aye.

7 Mr. Yarmuth.

8 Mr. Yarmuth. Aye.

9 The Clerk. Mr. Yarmuth votes aye.

10 Ms. Clarke.

11 Ms. Clarke. Aye.

12 The Clerk. Ms. Clarke votes aye.

13 Mr. Loeb sack.

14 Mr. Loeb sack. Aye.

15 The Clerk. Mr. Loeb sack votes aye.

16 Mr. Schrader.

17 Mr. Schrader. Aye.

18 The Clerk. Mr. Schrader votes aye.

19 Mr. Kennedy.

20 Mr. Kennedy. Aye.

21 The Clerk. Mr. Kennedy votes aye.

22 Mr. Cardenas.

23 Mr. Cardenas. Aye.

24 The Clerk. Mr. Cardenas votes aye.

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1 Chairman Upton.

2 Chairman Upton. Votes no.

3 The Clerk. Chairman Upton votes no.

4 The Chairman. Other members wishing to cast a vote or change
5 a vote? Mr. Johnson.

6 Mr. Johnson. No.

7 The Clerk. Mr. Johnson votes no.

8 The Chairman. Other members? Seeing none, the Clerk will
9 report the tally.

10 The Clerk. Mr. Chairman, on that vote there were 22 ayes and
11 29 nos.

12 The Chairman. Twenty-two ayes, 29 nos, the amendment is not
13 agreed to.

14 Are there further amendments to the bill? Seeing none, the
15 vote occurs on H.R. 5092. Those in favor will say aye.

16 [A chorus of ayes]

17 The Chairman. Those opposed say no.

18 [A chorus of nos]

19 The Chairman. Opinion of the Chair, the ayes have it. A roll
20 call was asked for. So a roll call is asked for. I would note that
21 when this roll call is done, vote has been called on the House.
22 We will recess until 8:00 p.m. Okay, 8 p.m., and the Clerk will
23 call the roll.

24 The Clerk. Mr. Barton.

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1 Mr. Barton. Yes.

2 The Clerk. Mr. Barton votes aye.

3 Mr. Whitfield.

4 Mr. Whitfield. Aye.

5 The Clerk. Mr. Whitfield votes aye.

6 Mr. Shimkus.

7 Mr. Shimkus. Aye.

8 The Clerk. Mr. Shimkus votes aye.

9 Mr. Pitts.

10 Mr. Pitts. Aye.

11 The Clerk. Mr. Pitts votes aye.

12 Mr. Walden.

13 Mr. Walden. Aye.

14 The Clerk. Mr. Walden votes aye.

15 Mr. Murphy.

16 Mr. Murphy. Aye.

17 The Clerk. Mr. Murphy votes aye.

18 Mr. Burgess.

19 Mr. Burgess. Aye.

20 The Clerk. Mr. Burgess votes aye.

21 Mrs. Blackburn.

22 Mrs. Blackburn. Aye.

23 The Clerk. Mrs. Blackburn votes aye.

24 Mr. Scalise.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 [No response.]

2 The Clerk. Mr. Latta.

3 Mr. Latta. Aye.

4 The Clerk. Mr. Latta votes aye.

5 Mrs. McMorris Rodgers.

6 [No response.]

7 The Clerk. Mr. Harper.

8 Mr. Harper. Aye.

9 The Clerk. Mr. Harper votes aye.

10 Mr. Lance.

11 Mr. Lance. Aye.

12 The Clerk. Mr. Lance votes aye.

13 Mr. Guthrie.

14 Mr. Guthrie. Aye.

15 The Clerk. Mr. Guthrie votes aye.

16 Mr. Olson.

17 Mr. Olson. Aye.

18 The Clerk. Mr. Olson votes aye.

19 Mr. McKinley.

20 Mr. McKinley. Aye.

21 The Clerk. Mr. McKinley votes aye.

22 Mr. Pompeo.

23 [No response.]

24 The Clerk. Mr. Kinzinger.

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1 Mr. Kinzinger. Aye.

2 The Clerk. Mr. Kinzinger votes aye.

3 Mr. Griffith.

4 Mr. Griffith. Aye.

5 The Clerk. Mr. Griffith votes aye.

6 Mr. Bilirakis.

7 Mr. Bilirakis. Aye.

8 The Clerk. Mr. Bilirakis votes aye.

9 Mr. Johnson.

10 Mr. Johnson. Aye.

11 The Clerk. Mr. Johnson votes aye.

12 Mr. Long.

13 Mr. Long. Aye.

14 The Clerk. Mr. Long votes aye.

15 Mrs. Ellmers.

16 Mrs. Ellmers. Aye.

17 The Clerk. Mrs. Ellmers votes aye.

18 Mr. Bucshon.

19 Mr. Bucshon. Aye.

20 The Clerk. Mr. Bucshon votes aye.

21 Mr. Flores.

22 Mr. Flores. Aye.

23 The Clerk. Mr. Flores votes aye.

24 Mrs. Brooks.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mrs. Brooks. Aye.

2 The Clerk. Mrs. Brooks votes aye.

3 Mr. Mullin.

4 Mr. Mullin. Aye.

5 The Clerk. Mr. Mullin votes aye.

6 Mr. Hudson.

7 Mr. Hudson. Aye.

8 The Clerk. Mr. Hudson votes aye.

9 Mr. Collins.

10 Mr. Collins. Aye.

11 The Clerk. Mr. Collins votes aye.

12 Mr. Cramer.

13 Mr. Cramer. Aye.

14 The Clerk. Mr. Cramer votes aye.

15 Mr. Pallone.

16 Mr. Pallone. I'm sorry. No.

17 The Clerk. Mr. Pallone votes no.

18 Mr. Rush.

19 Mr. Rush. No.

20 The Clerk. Mr. Rush votes no.

21 Ms. Eshoo.

22 Ms. Eshoo. No.

23 The Clerk. Ms. Eshoo votes no.

24 Mr. Engel.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 [No response.]

2 The Clerk. Mr. Green.

3 Mr. Green. No.

4 The Clerk. Mr. Green votes no.

5 Ms. DeGette.

6 Ms. DeGette. No.

7 The Clerk. Ms. DeGette votes no.

8 Mrs. Capps.

9 Mrs. Capps. No.

10 The Clerk. Mrs. Capps votes no.

11 Mr. Doyle.

12 Mr. Doyle. No.

13 The Clerk. Mr. Doyle votes no.

14 Ms. Schakowsky.

15 Ms. Schakowsky. No.

16 The Clerk. Ms. Schakowsky votes no.

17 Mr. Butterfield.

18 Mr. Butterfield. No.

19 The Clerk. Mr. Butterfield votes no.

20 Ms. Matsui.

21 Ms. Matsui. No.

22 The Clerk. Ms. Matsui votes no.

23 Ms. Castor.

24 Ms. Castor. No.

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1 The Clerk. Ms. Castor votes no.

2 Mr. Sarbanes.

3 Mr. Sarbanes. No.

4 The Clerk. Mr. Sarbanes votes no.

5 Mr. McNerney.

6 Mr. McNerney. No.

7 The Clerk. Mr. McNerney votes no.

8 Mr. Welch.

9 Mr. Welch. No.

10 The Clerk. Mr. Welch votes no.

11 Mr. Lujan.

12 Mr. Lujan. No.

13 The Clerk. Mr. Lujan votes no.

14 Mr. Tonko.

15 Mr. Tonko. No.

16 The Clerk. Mr. Tonko votes no.

17 Mr. Yarmuth.

18 Mr. Yarmuth. No.

19 The Clerk. Mr. Yarmuth votes no.

20 Ms. Clarke.

21 Ms. Clarke. No.

22 The Clerk. Ms. Clarke votes no.

23 Mr. Loeb sack.

24 Mr. Loeb sack. No.

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1 The Clerk. Mr. Loeb sack votes no.

2 Mr. Schrader.

3 Mr. Schrader. Aye.

4 The Clerk. Mr. Schrader votes aye.

5 Mr. Kennedy.

6 Mr. Kennedy. No.

7 The Clerk. Mr. Kennedy votes no.

8 Mr. Cardenas.

9 Mr. Cardenas. No.

10 The Clerk. Mr. Cardenas votes no.

11 Chairman Upton.

12 Chairman Upton. Votes aye.

13 The Clerk. Chairman Upton votes aye.

14 The Chairman. Other members wishing to cast a vote or change
15 their vote? Seeing none, the Clerk will report the tally. Reminder
16 as the Clerk does the tally that we are coming back at 8:00. We're
17 recessing until 8:00 to finish the last two bills.

18 The Clerk. Mr. Chairman, on that vote there were 29 ayes,
19 21 nos.

20 The Chairman. Twenty-nine ayes, 21 nos, the bill is agreed
21 to and favorably reported.

22 The committee stands in recess.

23 [Recess.]

24 The Chairman. All right, back in session here.

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1 The Chair will call up H.R. 3299 as forwarded by the
2 Subcommittee on Health on June 8th, and ask the Clerk to report.

3 [The Bill H.R. 3299 follows:]

4

5 *****INSERT 15*****

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1 The Clerk. H.R. 3299, to amend the Public Health Service Act
2 to insure preparedness for chemical, radiological, biological,
3 and nuclear threats, and for other purposes.

4 The Chairman. And without objection the first reading of the
5 bill is dispensed with, and the bill will be open for amendment
6 at any point. And I understand Mrs. Brooks has an amendment in
7 the nature of a substitute. And the Clerk will report the title.

8 [The Amendment offered by Mrs. Brooks follows:]

9

10 *****INSERT 16*****

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1 The Clerk. Amendment in the nature of a substitute to H.R.
2 3299 offered by Mrs. Brooks.

3 The Chairman. And without objection the amendment is
4 considered as read. The Staff will distribute the amendment, and
5 the gentlelady is recognized for five minutes in support of her
6 amendment.

7 Mrs. Brooks. Thank you, Mr. Chairman.

8 Out the outset, I want to begin by thanking my partner in
9 crafting this bill, Congresswoman Eshoo, who has truly been an
10 expert in this field. Our ability to craft this comprehensive bill
11 together proves that partisanship truly has no place when it comes
12 to protecting our homeland.

13 As an original author of Project Bioshield, Congresswoman
14 Eshoo crafted Project Bioshield. She knows how multilayered and
15 complicated our preparedness enterprise is. H.R. 3299 has
16 significant and real reforms to continue to strengthen and
17 expedite how we as a country are prepared to respond to biological
18 threats.

19 This amendment in the nature of a substitute does the
20 following: Requires BARDA and the CDC to coordinate medical
21 countermeasures for what's called the Strategic National
22 Stockpile. It removes outdated and bureaucratic steps in the
23 procurement contract process to expedite critical medical
24 countermeasures procurement contracts, and it returns

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1 contracting authority to the BARDA Director as is currently in
2 statute, although not currently in practice. It creates a Priority
3 Review Voucher Program for all material threats identified by the
4 Department of Homeland Security as direct threats to our national
5 security. And if you don't know what those material threats are,
6 they are things like anthrax, smallpox, cyanide threats, threats
7 that will kill volumes and volumes of people if infected
8 throughout our country.

9 And, finally, as the front line of any outbreak or biologic
10 weapon attack, our hospitals and first responders must be equipped
11 with the resources they need as we saw during the ebola outbreak
12 to safely and effectively respond.

13 Our bill requires the GAO to conduct a review of the Hospital
14 Preparedness Program and the Public Health Emergency Preparedness
15 Grants to insure that the goals are being met and to identify
16 potential readiness gaps.

17 There's a reason that six of the items -- there are six of
18 the items on the Material Threat List that has 13 items that have
19 no developed vaccine or treatment or whatsoever. That's because
20 medical countermeasures are incredibly challenging and unique.
21 On average, it takes 14 years to develop a medical countermeasure
22 with no guarantee of their success by the companies that undertake
23 them. Given the length of time it takes to develop a countermeasure
24 and the shear complexity and uncertainty of the process it's

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1 imperative that we keep our private sector partners engaged. The
2 PRV Programs have proven effective, zero cost to the taxpayer,
3 commonsense way of achieving this goal, and incentivizing
4 countermeasure development to protect the American people.

5 We have the support of the following groups: The American
6 Hospital Association, Trust for America's Health, the Department
7 of Army, the Alliance for Biosecurity, VC Investors in Biotech,
8 and the Blue Ribbon Study Panel on Biodefense. I'd like to ask
9 unanimous consent to submit their letters of support for the
10 record.

11 The Chairman. Without objection.

12 Mrs. Brooks. And with that, I'd like to yield the remainder
13 of my time to my partner on this bill, and a strong leader in
14 biodefense space, Congresswoman Eshoo.

15 Ms. Eshoo. I thank the gentlewoman both for your good words,
16 your outstanding work, and for being a terrific partner in this,
17 and I couldn't mean it more.

18 My colleagues, I know this bill very well because I wrote
19 it, and I wrote it with Mike Rogers in 2006, and it was signed
20 into law at the time. And it was on the heels, obviously, of the
21 post-9/11 era, and what we were being advised here in terms of
22 preparedness relative to bioterrorism.

23 Now, Mrs. Brooks has outlined the list of changes. Many of
24 them are small, but there are two that stand out that I think I

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1 want to emphasize because I think they are two areas that members
2 are not so familiar with. The one in terms of contracting is really
3 not a change. It was in the original legislation, and then it
4 changed within the bureaucracy. I believe -- we believe that this
5 belongs within BARDA because we have to have timeliness in terms
6 of approval. You can't have one product take 17 months to be
7 approved. We will not have a stockpile of what we need.

8 What is new in the bill, which I think is a very important
9 change, is the Priority Review Voucher. Understand there's no
10 public money in this, they are private dollars. Homeland Security
11 comes up with the list. If a company chooses to use the Priority
12 Review Voucher, the FDA must approve it.

13 So I think these are sound recommendations. I think they are
14 important for our national security. I think the stockpile of what
15 needs to be created in terms of a biodefense for our country is
16 absolutely essential, and I think that BARDA will be strengthened
17 in order to do the job that needs to be done in order to protect
18 our country.

19 So I don't think I have any of your time left, Congresswoman
20 Brooks, but I thank you for yielding time to me, and again for
21 your partnership and wonderful work.

22 The Chairman. The gentlelady's time has expired. Other
23 members wishing to speak on the amendment in the nature of a
24 substitute? Seeing none, the vote occurs on that amendment. All

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1 those in favor will say aye.

2 [A chorus of ayes.]

3 The Chairman. Those opposed, nay. In the opinion of the
4 Chair, the ayes have it, the ayes have it, and the amendment in
5 the nature of a substitute is agreed to.

6 Are there other amendments to the bill? Gentleman from New
7 Jersey has an amendment at the desk. The Clerk will call the title

8 -- -

9 [The Amendment offered by Mr. Pallone follows:]

10

11 *****INSERT 17*****

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1 Mr. Pallone. The first one is number 2.

2 The Chairman. The Clerk will read the title.

3 The Clerk. Amendment to the amendment in the nature of a
4 substitute -- -

5 The Chairman. Oh, wait, wait.

6 Mr. Pallone. Oh, I'm sorry, it's 01. I apologize; 01 relating
7 to the contract authority.

8 The Clerk. Amendment to the amendment in the nature of a
9 substitute to H.R. 3299 offered by Mr. Pallone.

10 The Chairman. And the amendment will be considered as read.
11 The Staff will distribute the amendment, and the gentleman from
12 New Jersey is recognized for five minutes in support of his
13 amendment.

14 Mr. Pallone. Thank you, Mr. Chairman.

15 As was mentioned by the sponsors, the bill delegates
16 contracting authority directly to the BARDA Director, and the
17 purpose of this amendment is to keep the current structure; in
18 other words, where the Assistant Secretary for Public Response
19 or ASPR, has to approve it. What we're trying to do with this
20 amendment is not eliminate the level of approval by the Assistant
21 Secretary, because I think it protects the integrity of the
22 contracting process.

23 So, Mr. Chairman, since the reorganization of the Office of
24 the Assistant Secretary of Preparedness and Response at ASPR,

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1 which consolidated organizational wide contracting activities,
2 BARDA has experienced an acceleration in the delivery of medical
3 countermeasures. For example, the total 23 products that BARDA
4 has supported that received FDA approval licensure or clearance,
5 14 of those approvals have occurred since 2011, and five have
6 occurred in the last 16 months. And BARDA is also currently
7 supporting a pipeline of over 100 more.

8 In addition to the success with delivering medical
9 countermeasures, the AMC's execution of BARDA contracting
10 activity has exceeded governmental benchmarks. The
11 Department-wide benchmark for contract issuance is 180 days, the
12 average for BARDA contracts is 129 days. The last seven major
13 acquisitions have actually occurred even faster reaching
14 completion in 90 days with only two of those contracts exceeding
15 100 days.

16 Additionally, the contracting office has proven that it can
17 deliver in times of emergency. For example, in response to the
18 FDA guidance that it was going to require blood collection in areas
19 with active Zika transmission to be sought, the contracting office
20 issued contracts to support the emergency delivery of blood to
21 Puerto Rico within six business days. So based on this, I agree
22 with Dr. Hatchett, the Acting Director of BARDA who stated at our
23 hearing on this legislation that "after looking at the data it
24 does not support the restructuring required by this bill. The data

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1 makes clear the contracting office is exceeding performance
2 expectations and helping BARDA fulfill its mission to advance
3 national security by helping to protect against terrorism and
4 other public health threats. In addition to concluding the move
5 is unnecessary, I also have concerns with problems that would
6 arise from the proposed change. I have concerns about the
7 delegation of the function to negotiate and enter into contracts,
8 grants, and cooperative agreements to the BARDA Director.
9 Currently, BARDA enters into contracts through the office that
10 asks for its parent organization, and this structure protects the
11 integrity of the contracting process."

12 After Secretary Sebelius provided Congress with notice and
13 published the required announcement in the Federal Register in
14 2010, contracting offices were removed from BARDA and other
15 divisional entities within ASPR and consolidated. The
16 restructuring of the contract offices was done to streamline
17 ASPR's contracting activity to bolster program integrity, and to
18 insure that ASPR and all of its operating divisions conduct their
19 business without either the perception or potentially the reality
20 of undue influence by program officials. And that restructuring
21 allowed the office or the head of contracting activity to be
22 successful. It basically removed the need for the contracting
23 office to go through an additional layer of approval.

24 So my point is that the current structure which is consistent

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1 with procurement practices across the federal government insures
2 the right balance between expert scientists that advance our
3 national preparedness and expert contracting professionals that
4 insure the government is getting the best value for every taxpayer
5 dollar. And I think this integrity minded structure established
6 by ASPR has not only contributed to a steadily improved
7 contracting process, but also one that has successfully withstood
8 the few protests presented to the organization.

9 I don't want to continue with this, Mr. Chairman, but my point
10 is, I don't really see the need for the restructuring to have to
11 eliminate the overview, if you will, of ASPR and just have the
12 contract -- the BARDA Director do the contracting directly. I'll
13 yield back the balance of my time.

14 The Chairman. Gentleman yields back. The Chair recognizes
15 Mr. Flores.

16 Mr. Flores. And I can defer to Ms. Eshoo, if you'd like her
17 to go first. She was holding her hand up first. You want me to
18 go?

19 The Chairman. Please.

20 Mr. Flores. Okay. Thank you, Mr. Chairman.

21 I applaud the great work of Congresswoman Eshoo, and also
22 Congresswoman Brooks on this bill. The Strengthening Public
23 Health Emergency Response Act is about protecting our
24 constituents from public health emergencies and biochemical

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1 attacks. This bill seeks to create an environment where the
2 private sector and the federal government can work
3 collaboratively in the most efficient manner to create medical
4 countermeasures, known as MCM, to protect the American people.

5 An important component of this bill is that it repairs the
6 damage done to this goal by the HHS attempts to arbitrarily modify
7 the BARDA contracting progress. And so contrary to the goal of
8 this bill, the Pallone Amendment seeks to limit BARDA's
9 contracting authority. This amendment jeopardizes U.S. national
10 security by undermining efficiency and, ultimately, slowing down
11 MCM development at BARDA as it may continue to face roadblocks
12 and be slow an inefficient.

13 When government is an impediment, it discourages many
14 private sector partners and public sectors partners out of this
15 critical work leaving the American people vulnerable to epidemics
16 and biowarfare attacks.

17 When BARDA was created in 2006, Congress and this committee
18 gave the agency the sole authority to negotiate and execute its
19 biomedical countermeasure advance development contracts. And
20 Congress on a bipartisan basis viewed this contracting authority
21 as a critical component of BARDA's unique national security
22 mission. And it was intended to function similar to the Department
23 of Defense with nimble and flexible contracting procedures.
24 Despite the intent of Congress, BARDA's contracting authority was

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1 removed by HHS in 2009, and authority over all of BARDA's contracts
2 was moved to the Office of Acquisitions Management Contracts and
3 Grants, ACMG, within the Office of the Assistant Secretary for
4 Preparedness and Response, ASPR. This cumbersome arrangement has
5 created confusion, unnecessary delays, and uncertainty regarding
6 time-sensitive medical countermeasure contracts, and is counter
7 to BARDA's mission to be flexible, nimble, and efficient.

8 ACMG's review and approval process is often slow,
9 burdensome, and inefficient. For example, at BARDA's insistence
10 insurance companies -- excuse me -- companies often respond to
11 urgent requests to submit proposals within a 24 to 48-hour
12 turnaround only to have these proposals languish in ACMG's review
13 process for multiple weeks or even months. ACMG does not appear
14 to have an understanding or an appreciation of the complexities
15 of vaccine or MCM development and how lengthy, and flexible, and
16 burdensome review can delay timelines, or worse cause entities
17 to question their partnership with HHS.

18 For example, Texas A&M University is my congressional
19 district, and operates one of three vaccine research and
20 development centers for BARDA. This institution has experienced
21 significant frustrations and delays in dealing with the
22 contracting schematic that was disconnected from the BARDA
23 mission. The contracting team did not appear to understand many
24 of the basic tenets of cost reimbursement contracts leaving the

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1 State of Texas and Texas A&M as an institution having to cover
2 capital outlays beyond any reasonable period that the private
3 sector would consider acceptable.

4 Furthermore, the contracting team was not in step with the
5 scope and mission, the request from BARDA's Director's office.
6 In a time of national emergency, the public cannot afford delays
7 or misalignment of the process with the mission. The contracting
8 authority needs to be aligned now, not as an afterthought
9 following a national emergency. There is broad agreement among
10 Congress and independent experts that BARDA should be allowed to
11 negotiate, manage, and award its own contracts as it has done
12 effectively and efficiently in the past. BARDA's former Director
13 who served for the last 10 years even testified to this committee
14 that restoring BARDA's contracting authority would improve MCM
15 development.

16 In 2015, the Blue Ribbon Study Panel on Defense recommended
17 that the contracting authority be returned to BARDA citing the
18 importance of BARDA's national security mission within HHS. So
19 returning contracting authority back to BARDA would not cost the
20 taxpayers a dime, it would not put any burdens on HHS, and it would
21 not jeopardize the integrity of the contracting process. It would,
22 however, be consistent with how Congress envisioned BARDA to
23 function.

24 I urge my colleagues to oppose the Pallone Amendment and to

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1 allow contracting authority for BARDA, and I appreciate
2 Congresswoman Eshoo and Congresswoman Brooks for fixing this
3 critical issue with respect to the way HHS operates today. Thank
4 you, and I yield back the balance of my time.

5 The Chairman. The gentleman yields back. Other members
6 wishing to speak? The gentlelady from California, Ms. Eshoo.

7 Ms. Eshoo. Thank you, Mr. Chairman. I move to strike the last
8 word.

9 My colleagues, this is a very important part of the bill,
10 and I know at 8:30 at night the last thing you probably feel like
11 even listening to are the innards of contracts at a small agency
12 that most of you are not familiar with. But this is -- this really
13 goes to the heart of how this very small but supposed to be limber
14 agency is to work, because if the contracting is stretched out,
15 not effective, not efficient, then you're not going to get
16 product. And that's what we're after, that's why we set this
17 operation up.

18 Now, as Congressman Flores, and I appreciate your good words,
19 pointed out there was Blue Ribbon Study Panel on Biodefense.
20 Former Senator Joe Lieberman was -- and he was the former Chairman
21 of the Senate Homeland Security Committee, and the former
22 Secretary of Homeland Security, Tom Ridge, published an 82-page
23 report on the subject, and it included a recommendation that BARDA
24 contracting authorities be reinstated.

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1 Now what happened from the time the ink dried when it became
2 law that stipulated that BARDA would do the contracting, and now
3 our Ranking Member is offering an amendment to keep it to where
4 it has drifted to. And it has drifted, it has not worked out well.

5 I want to offer a quote from a 2011 story in the New York
6 Times Magazine which highlighted the inefficiencies of the
7 contracting situation. And it was stated that the person that was
8 -- it had drifted to "had removed from BARDA all the contracting
9 officers instructing them to report to her instead of Robinson."
10 I don't know how these people took away what was originally what
11 was in the law, but if it were working well, you know what, I'd
12 let it fly. I wouldn't be talking to you at 8:30 at night about
13 this. But it was said by those that worked with them, "We actually
14 spend as much time managing our contracts as we do trying to
15 develop our drugs." And that's not why we did the legislation,
16 it's not why it became law.

17 Now Dr. Robinson, who headed up BARDA for 10 years said, "If
18 there was anything to be done, it was to keep the contracting in
19 BARDA." I think that, obviously, all the -- everything that is
20 a part of not only transparency but what needs to be kept and put
21 into place relative to conflict of interest, all of that have to
22 guide contracting. But if it is not working and operating
23 efficiently, I think that Congress needs to say something and step
24 in on this. Otherwise, most frankly, I wouldn't bother with it.

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1 If I thought this was a pesky fly, I wouldn't -- in terms of an
2 issue, I wouldn't place this much of an emphasis on it. But it
3 is very important.

4 And how did we model the original legislation that became
5 law? We modeled it after DARPA. We modeled it after DARPA. DARPA
6 does its own contracting, and DARPA is hailed by all of us on both
7 sides of the aisle. So we worked hard, and I think that we produced
8 a product at that time that really made sense and has worked.

9 So it isn't too often I disagree with the Ranking Member,
10 but I do on this one. The other agency that seems to have taken
11 over this contracting issue or operation is very unhappy. And I
12 met with the doctor who heads it up, and it was not an easy meeting;
13 many questions left unanswered. And she promised that she would
14 get recommendations to me to improve the legislation, and we've
15 never received such.

16 So given all of this backdrop, I really recommend that this
17 suggestion by way of an amendment not be accepted for all the
18 reasons that I stated. It's modeled after DARPA, the original
19 Director said this is the heart of the program in terms of
20 efficiency and timeliness, which is essential for bioterrorism
21 products. And there was a commission or a Blue Ribbon Committee
22 that included that recommendation for contracting authorities
23 being reinstated. I think that's one heck of a record on this item,
24 and I thank -- I yield back the non-balance of my time.

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1 The Chairman. The gentlelady's time is expired. Other
2 members wishing to speak on the amendment? Seeing none, the vote
3 occurs on the amendment offered by the gentleman from New Jersey.
4 All those in favor say aye.

5 [A chorus of ayes.]

6 The Chairman. Those opposed say no.

7 [A chorus of nos.]

8 The Chairman. Opinion of the Chair, the nos have it, the nos
9 have it, the amendment is not agreed to.

10 Are there other amendments to the amendment -- the gentleman
11 from New Jersey has another amendment?

12 Mr. Pallone. Yes, this one is number 2.

13 The Chairman. Number 2, and the Clerk will report the title
14 of the amendment.

15 [The Amendment offered by Mr. Pallone follows:]

16

17 *****INSERT 18*****

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1 The Clerk. Amendment to the amendment in the nature of a
2 substitute to H.R. 3299 offered by Mr. Pallone.

3 The Chairman. And the amendment will be considered as read.
4 The Staff will distribute the amendment, and the gentleman is
5 recognized for five minutes in support of his amendment.

6 Mr. Pallone. Thank you, Mr. Chairman.

7 The substitute that we voted on today to H.R. 3299 would
8 create a new permanent Priority Review Voucher, or PRV program
9 for medical countermeasures. And for this reason, I can't support
10 the bill as amended by the substitute.

11 I have on several occasions voiced concerns with extending
12 PRV programs to include medical countermeasures as I believe it's
13 an unnecessary incentive in this space. A 2014 Congressional
14 Research Service report found that since 2004, the federal
15 government has spent over \$3 billion procuring medical
16 countermeasures, and this is in addition to the hundreds of
17 millions of dollars HHS and DoD awarded drug companies each year
18 to support medical countermeasure research and development.

19 For example, HHS reported it would spend over \$830 million
20 during the 2015 fiscal year to support medical countermeasure
21 research, development, and procurement through BARDA and Project
22 Bioshield. Providing an additional PRV incentive, the last of
23 which sold for \$350 million to drug companies already receiving
24 significant taxpayer support seems inappropriate and

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1 unnecessary. However, if this legislation is enacted, I believe
2 it is important to insure it is actually incentivizing new
3 research and development of medical countermeasures. And as such,
4 I'm offering an amendment to sunset the program in 2023 tied to
5 a future reauthorization of the Pandemic and All-Hazards
6 Preparedness Act or PAHPA. A sunset will provide Congress an
7 opportunity to evaluate the effectiveness of the medical
8 countermeasure PRV program and determine if the program's
9 benefits outweigh its cost. And this sunset date will also allow
10 us to evaluate the program in the broader context of national
11 preparedness during PAHPA reauthorization discussions.

12 In other important areas, such as incentivizing drug
13 development to help children, we recognize the value in periodic
14 program assessment. For example, the Rare Pediatric Disease PRV
15 program, the Best Pharmaceuticals for Children Act, and the
16 Pediatric Research Equity Act all included initial sunset dates.
17 In fact, BPCA and PREA, which offer additional exclusivity to drug
18 manufacturers who conduct pediatric studies were only enacted for
19 five years, and not made permanent until there was significant
20 experience with this incentive.

21 We recognize the importance of evaluating our legislative
22 choices in these situations, and I question how we can justify
23 not taking a similar approach when it comes to medical
24 countermeasure development. So I offer this sunset to insure an

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1 opportunity for lawmakers to assess if this PRV program, if
2 enacted, is improving our ability to protect American citizens
3 from material threats before we permanently extend such a valuable
4 award to drug companies.

5 The need for evaluations rings especially true in the PRV
6 context given the lack of evidence these programs work as
7 intended. As we heard at the May 19th hearing on H.R. 3299, there's
8 been only one study of existing PRV Programs. In this study, GAO
9 found a lack of evidence demonstrating the Rare Pediatric Disease
10 Program was incentivizing new investment in drug R&D. While we
11 do not know if PRV programs are an effective incentive for drug
12 development, we do know the strain these programs place on FDA.
13 We heard from bill supporters that PRV programs are cost-neutral;
14 however, this is not true as they consume significant FDA
15 resources, resources funded by tax dollars.

16 When FDA receives a PRV, it must divert resources from
17 existing work to expedite review of a drug that may under normal
18 circumstances be a lower public health priority. PRVs also reduce
19 the time FDA reviewers have to perform complex drug reviews from
20 10 to six months. We heard from FDA during the May 19th legislative
21 hearing that the fee a company pays when redeeming a PRV does not
22 cover the cost of these expedited drug reviews and, thus, the
23 American taxpayer foots the remaining bill.

24 Now some view a sunset for the medical countermeasure PRV

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1 Program does not take into account the unique nature of medical
2 countermeasure development, and could result in companies not
3 entering this space. And I would, again, note that drug
4 manufacturers already receive considerable financial support
5 from the federal government to develop medical countermeasures.
6 This financial support has been a sufficient incentive for drug
7 companies to develop 89 approved MCMs since 2000. Others suggest
8 that seven years is not long enough to fully assess if the PRV
9 is working in the medical countermeasure space; however, this does
10 not mean we should instead enact a permanent program as after seven
11 years we'll have an understanding of any new investment in medical
12 countermeasure development, including any new entrants.

13 While we do not want to understand if the PRV is an effective
14 incentive for new research and development for medical
15 countermeasures, we must also understand how a third PRV program
16 impacts FDA and the agency's ability to meet agreed upon drug
17 review timelines.

18 I want to go on but my point, Mr. Chairman, is that this
19 amendment is good policy. As lawmakers, I think it's our duty to
20 insure the legislation we enact benefits the American public, and
21 I think a sunset will provide Congress an opportunity to evaluate
22 the medical countermeasure PRV program and determine if extension
23 is in the best interest of national preparedness. I yield back.

24 The Chairman. The gentleman yields back. The Chair would

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1 recognize the gentleman from New York, Mr. Collins.

2 Mr. Collins. I'd like to strike the last word.

3 Sunsetting this PRV Program after seven years would
4 dramatically reduce the impact of the program. A seven-year sunset
5 would only insure that companies that are already in this space
6 would get rewarded for their work, which is important; however,
7 that's not the full purpose of the program.

8 This Priority Review Program as written provides companies
9 to invest in this space in the long term. The uncertainty of a
10 reauthorization provides enough risk to deter companies from
11 going into this space.

12 There are two other Priority Review Voucher Programs, one
13 for Rare Pediatric Diseases, and other for Neglected Tropical
14 Diseases. There's bipartisan support for these programs because
15 we all agree that it's incredibly important that we incentivize
16 innovation in this space. The Neglected Tropical Disease Program
17 does not have a sunset, but the Pediatric Rare Disease PRV Program
18 does.

19 In GAO's review of the Pediatric PRV Program, they were told
20 by patient advocacy groups that a sunset was limiting new research
21 in pediatric diseases. GAO also found that a sunset created
22 ambiguity for industry that, therefore, diminishes the program's
23 appeal. Creating a sunset here would do the exact same thing.

24 We know that these threats are not going away. I do not think

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1 this program should end until we have antidotes for all of them,
2 and that's exactly what this bill does. We need to be prepared,
3 and we need to know we are not prepared right now. We know that
4 the best preparedness for these threats is a stockpile of drugs
5 and vaccines that can be quickly dispensed if and when a threat
6 materializes.

7 I want to thank Mrs. Brooks and Ms. Eshoo for their leadership
8 on this vital piece of legislation. I agree with what Ms. Eshoo
9 said in her opening statement; as Representatives it is our
10 highest responsibility to defend Americans. And I yield back.

11 The Chairman. The gentleman yields back. Other members --
12 the gentlelady from California is recognized for five minutes.

13 Ms. Eshoo. Thank you, Mr. Chairman.

14 I rise in opposition to the amendment, and let me walk members
15 through why. When you look at the amendment that was passed out,
16 the first thing it does is to terminate the authority of the
17 Secretary not to award any Priority Review Vouchers, and then it
18 goes on to put in a review time that is much briefer than what
19 we're requesting.

20 Now, I think that I went through the value of Priority Review
21 Vouchers, why they are important? And I think that members need
22 to appreciate the following facts. A very small number of
23 companies in the private sector engage in the MCM development.
24 This is not big business. You need to understand that. And for

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1 those that do, the only buyer of their products is the United
2 States Federal Government. All right? So we're the buyer, and you
3 know why we are the buyer. We need these products and we want them
4 developed for the protection of the American people.

5 I think that there is a risk of -- let me put it this way.
6 There's hardly a guarantee that there will be a purchase at all,
7 and you've got to take that into consideration. A PRV is
8 essentially a tool, it's adding a tool in the toolkit along with
9 R&D investments to encourage companies to develop these much
10 needed MCMs. So, you know, this is all-there's risk-taking, and
11 you want the private sector to respond. Why we would kill this?
12 I really have trouble getting my head around that.

13 In terms of the timing, let me just point out a few facts
14 about three currently approved products, three currently approved
15 products which would have qualified for PRV and the average time
16 that it took to develop them. A product to treat patients with
17 inhalational anthrax, the time to approval, 13 years. The
18 amendment says stop at seven. A product to treat adult and
19 pediatric patients with inhalational anthrax when alternative
20 therapies are not appropriate, time to approval 12 years. The
21 amendment says seven. A product to treat symptomatic botulism,
22 time to approval 17 years. The amendment says cut it off at seven.

23 I don't know what the rationale of this is. The amendment
24 really represents circling our wagons and shooting at ourselves

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1 because this is all meant to develop what we need and to incent
2 the people that are going to do the research to come up with the
3 product where the federal government is the only buyer of the
4 product. So it's -- there's either a misunderstanding about what
5 this represents, and I'm trying to make it almost conversational
6 so that you understand it, and that you are comfortable with it.

7 The bill includes a very thorough GAO study which is going
8 to give us critical information on how this program is working
9 so we can address fixing it in the future, but if you chop it off
10 and say you're going to stop everything in seven years, then you
11 might as well just fold the tent and say BARDA go away, we're just
12 not going to do this any more, because there has to be -- you have
13 to build in incentives in order to make this thing work.

14 So I appreciate your listening, and I hope I've added
15 something to this debate relative to the amendment because I think
16 this amendment just collapses the whole thing. I think you have
17 to have reviews, but I think that seven years just doesn't work.
18 Thank you, and I yield back.

19 The Chairman. Further amendments, or further members wishing
20 to speak on the amendment? The gentleman is recognized for five
21 minutes. Gene, use the mike.

22 Mr. Green. -- our defense capabilities within the
23 Department of Health and Human Services. I strongly support the
24 intent of the legislation and we tried to work across party lines

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1 and improve and strengthen the bill.

2 What the Pallone Amendment Number 2 would do would give
3 Congress an opportunity to review the success or lack of success
4 instead of having a limitless bill, which is what the current
5 substitute we adopted does. This legislation draws on the recent
6 Blue Ribbon Study Panel of Biodefense and makes targeted reforms
7 to streamline existing programs, enhance coordination between
8 agencies, and develop better data on our preparedness on the
9 ground. However, I also have concerns about the provision to
10 create a new incentive for medical countermeasures, MCMs,
11 development. We tried to reach an agreement but unlike the process
12 we undertook with the 21st Century Cures, the changes we would
13 need to make were not accepted. And, unfortunately, I can't
14 support the bill, but I do support the Pallone Amendment.

15 The amendment in the nature of a substitute that we adopted
16 would establish a new Priority Voucher Program, Review Voucher
17 Program, PRV, that made do little to incentivize novel needed
18 treatments, drain valuable resources at the FDA, and undermine
19 the Neglected Tropical Diseases, the NTDs, and Rare Pediatric
20 Diseases, the PRV Programs by diluting the market value of
21 vouchers. Creating a new PRV Program without addressing loopholes
22 that impede the NTD and PRV program is a missed opportunity.

23 Further, the lack of data demonstrating that two existing
24 PRV Programs are working as intended, or if a new PRV Program for

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1 medical countermeasures will be effective makes it unwise to
2 establish a new program permanently. That's why the Pallone
3 Amendment puts some limit on it. Although, Mrs. Capps has an
4 amendment that we'll see in a few minutes, she has an amendment
5 on the floor, so I'll be introducing it, it would limit it to 12
6 years, which is much better than the Pallone Amendment.

7 The development process, market forces, and role of
8 government in the MCM space is distinct. At the very least,
9 Congress should reserve the ability to exercise oversight on this
10 new incentive rather than authorize it in perpetuity without
11 understanding the necessity or effectiveness. While I appreciate
12 the intent of the provision, I continue to believe that the best
13 way to incentivize MCM development is robust, stable funding
14 similar to the Project Bioshield Special Reserve Fund, the SRV,
15 created in 2004.

16 I support many aspects of this legislation. I thank my
17 colleagues for their commitment for the Biodefense capability.
18 Unfortunately, conversations and commitment to find consensus
19 failed, and that's why I'm supporting the Pallone Amendment to
20 have some limit. But we will see another amendment in a few
21 minutes, and I'll yield back.

22 The Chairman. The gentleman -- -

23 Mr. Green. I'm glad to yield to my colleague from Maryland.

24 Mr. Sarbanes. Thank the gentleman for yielding.

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1 The sunseting strikes me as a reasonable path to take here.
2 I appreciate that there may be some arguments about the impact
3 sunseting could have with respect to the Rare Pediatric Disease
4 development, or Neglected Tropical Disease, but I think it's
5 apples and oranges to compare those to medical countermeasures
6 in terms of the development there. There's evidence that the FDA
7 is doing pretty well in terms of making sure those MCMs are being
8 developed, and even though there may be some examples, and
9 Congresswoman Eshoo has pointed to those, and that's fair to do
10 where development of a particular MCM could take an extended
11 period of time, I would imagine there's also a fair number of --
12 there will be a fair number of opportunities for development of
13 MCMs in a lesser period of time that could offer some examples
14 of whether the PRV process is a useful one with respect to MCMs
15 and do that within the seven-year time frame that's being proposed
16 for sunseting.

17 So if the end goal here with respect to MCMs is to insure
18 that we are developing, and there's plenty of evidence that that
19 is happening without a PRV Program, and I think there will be
20 plenty of examples of how development with a PRV could occur within
21 a seven-year period for us to judge the progress of that, or the
22 potential of that program for further extension. And so for those
23 reasons, it strikes me that that seven-year sunset proposal is
24 a reasonable one. And I yield back.

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1 The Chairman. The gentleman's time is expired. The Chair
2 recognizes the gentlelady from Indiana, Mrs. Brooks.

3 Mrs. Brooks. Thank you, Mr. Chairman. I move to strike the
4 last word.

5 I'd like to remind and actually indicate that I've been
6 informed that of the 13 material threats listed by Department of
7 Homeland Security, in fact, six of the 13 nothing is going on right
8 now. There is no treatment, there is no diagnostic, there is no
9 vaccine, there is nothing. So it is a mistake to presume that
10 companies are working on all of them; they are not. And so if we
11 want to gamble and assume that the terrorists who might be looking
12 at this, or naturally occurring, or if there is a release of one
13 of these products mistakenly, we're going to be taking a chance
14 on what we are prepared for.

15 I appreciate that yes, this is creating a permanent program;
16 however, we worked very hard in listening to the Ranking Member's
17 concerns, and at his request in the amendment in the nature of
18 the substitute we added a new study that was not in the original
19 bill, an incredibly thorough GAO report that wasn't in our
20 original bill that requires an initial assessment of this program
21 after the first 10 years, and then a final report at 16 years.
22 So this does allow future evaluation of the program, which I think
23 would address the Ranking Member's concern. So I don't understand
24 why we would limit our private sector companies and not providing

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1 them this incentive to try to engage in this space in a more robust
2 way than they are.

3 So, effectively, as the Congressman from New York said, once
4 we do have a medical countermeasure for all of these threats, the
5 13 threats, this is going to go away, but we don't have it right
6 now. We just don't. We're not ready. And this isn't just myself
7 and Congresswoman Eshoo saying it, this is what the Biodefense
8 Panel that went around the country and talked to our experts all
9 around the country led by Senator Lieberman and Governor Ridge.
10 And so for that reason, we tried with this GAO report to satisfy
11 your concern about the permanency. We can -- Congress will take
12 a look at this again when GAO does its analysis that's in our bill,
13 and for those reasons I would object to a sunset, and yield back.

14 The Chairman. The gentlelady yields back. The gentlelady
15 from California, Ms. Eshoo.

16 Ms. Eshoo. Thank you, Mr. Chairman.

17 I will present an area that is known for its risk-taking.
18 Everyone knows, I mean the -- I think to every person on the
19 committee, to a person on the committee, I should say, have
20 traveled to my district, so you know that it's in our DNA to be
21 risk-takers. I want to point out that this legislation is not about
22 taking risks. It's the opposite, because this is an area where
23 we can't afford to take risks.

24 I don't know where these numbers are coming from. One is

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1 seven, one is nine, something else, what I idea. We need to have
2 product in our toolbox if, in fact, any of these attacks are made
3 on our country. What are we doing? What are -- I don't understand
4 where this seven years to cut things off because that makes it
5 safer. I think we may be thinking of some other issues, maybe some
6 other drug issues, maybe resentment against drug companies, and
7 previous debates about other issues. That's not what this thing
8 is, and I'm speaking to my own side on this.

9 This is about developing the products that we need. And, yes,
10 if someone applies for a Priority Review Voucher and the FDA
11 reviews it and approves it, and that comes from the list of
12 Homeland Security where they have identified what we need, what
13 is wrong with that? That's airtight, so we should not have any
14 risk in this, as far as I'm concerned. We should leave here feeling
15 very satisfied that we have the tightest case for what this country
16 needs. If, God forbid, there is an attack, we need to be prepared
17 for it. That's what this is. This isn't a favor to me, Anna Eshoo.
18 This isn't some thing that Susan Brooks and I just cooked up. It's
19 based on what has already worked, on what the recommendations of
20 national -- people of national stature and expertise have
21 recommended. That's what this is about.

22 So I would ask you, as uncomfortable as it is, and I think
23 that we have some disputes inside agencies. I think there are some
24 people inside agencies that don't like the idea that they may have

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1 to review and approve something. Well, you know what, I admire
2 them. I have supported them all of my life in terms of their public
3 service, but we're the ones that are elected, they're not in plain
4 English.

5 So I don't support this amendment because I think it's not
6 well-founded. I think it's not well-founded. And to the gentleman
7 from Texas, you never offered to speak to me about anything. And
8 if you had, I would have. So with that, I think -- -

9 Mr. Green. If the gentlelady would yield.

10 Ms. Eshoo. I do have time. Sure.

11 Mr. Green We didn't talk, but I know our Staffs talked and
12 there was no movement in it. And this is something, like I said,
13 we worked on similar legislation over the last couple of years.
14 And my concern is that, you know, we reauthorize legislation all
15 the time, and maybe this amendment is not correct, but maybe the
16 one that Congresswoman Capps has is at 12 years will give that
17 kind of time. But we'll deal with that amendment as it comes up.

18 Ms. Eshoo. Well, reclaiming my time.

19 Mr. Green. Thank you. I yield -- -

20 Ms. Eshoo. It was a -- I know that you said that we didn't
21 come to an agreement, but I want members to know that you didn't
22 seek me out. If you had, I would have been glad to sit down and
23 talk to you. With that, I yield back the balance of my time.

24 The Chairman. The gentlelady yields back. I'd just like to

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1 note, I've just been told from the guy at the end of the hall,
2 end of the dias here that votes on the floor are going to start
3 a little earlier than we suspected, literally in about 10 minutes.
4 So I'd like to finish this debate on this amendment, and do the
5 next one, and get to final. And I think we may have to move the
6 next bill until tomorrow, unless we come back after. You'll just
7 let everybody have that notice. And the gentlelady from Illinois,
8 you have five minutes.

9 Ms. Schakowsky. Thank you. I support the Ranking Member's
10 amendment, but I want to say even if this amendment were to be
11 adopted, I still believe that the underlying legislation is
12 fundamentally flawed.

13 Of course, I agree with my colleagues that we need to address
14 the Biodefense needs, but I am disappointed that this bill fails
15 to make the needed improvements to the Priority Review Program
16 for Tropical Diseases. In fact, it creates an entirely new similar
17 incentive program for drug manufacturers, and we're missing an
18 opportunity to fix the Priority Review Voucher Program for
19 Tropical Diseases with this legislation. Instead, we're doubling
20 down by creating a new program with all the same problems.

21 In a March 29th letter to this committee, concerns were
22 raised by Doctors Without Borders, the TB Alliance, and Drugs for
23 Neglected Disease Initiative, among others, that it is difficult,
24 and sometimes impossible to access drugs approved under the

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1 Tropical Disease Program, and this is because there is no
2 requirement the drug sponsors even make the drug available for
3 purchase. I want to emphasize that, there's no requirement that
4 drug sponsors even make the drug available for purchase.

5 In addition, there is little evidence that Priority Review
6 Voucher Programs are incentivizing drug manufacturers to invest
7 in research and development. Of the three Priority Review Vouchers
8 awarded under the Tropical Disease Program, two were awarded to
9 drugs that had been used for years outside the United States
10 without those drug companies conducting any new research. And this
11 seems counter to the intent of Congress when passing this
12 legislation.

13 When H.R. 3299 was passed by the Health Subcommittee on June
14 7th, I was pleased that it included bipartisan language to fix
15 some of the problems in the Tropical Disease Priority Review
16 Voucher Program. However, today that language has been removed
17 from H.R. 3299, and instead of fixing these problems, the bill
18 completely reverses course by creating a new permanent Priority
19 Review Voucher Program for material threat medical
20 countermeasures.

21 I simply do not agree that we need to provide additional
22 incentives to pharmaceutical companies in order to get them to
23 purchase medical countermeasures. First, there is no evidence
24 that the FDA is not already approving medical countermeasures in

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1 a timely manner. The FDA already has the authority to designate
2 a medical countermeasure for a six-month Priority Review. Since
3 2000, the FDA has approved 89 medical countermeasures and 17
4 supplemental changes to already approved drugs.

5 Additionally, often drug manufactures that produce medical
6 countermeasures receive federal funding for their research and
7 development costs. And once a drug is approved, the federal
8 government spends billions of dollars purchasing these products
9 in order to stockpile them. Despite the substantial benefits, this
10 bill provides even greater incentives to pharmaceutical
11 manufacturers through the creation of a fraud -- a flawed Priority
12 Review Program. Similar to the Tropical Disease Program, Priority
13 Review Vouchers could be awarded for a drug previously approved
14 outside the United States without any requirement that the
15 manufacturers do any research and development additionally.

16 A Priority Review Voucher could be awarded to a drug that
17 does not fulfill any existing need for the federal government.
18 This new incentive program would not expedite FDA's review of
19 these drugs, or the time it would take for a product to come to
20 market. It would only award a drug company a Priority Review
21 Voucher that it could then redeem for any drug of its choosing,
22 or sell to the highest bidder.

23 These vouchers are incredibly lucrative for pharmaceutical
24 companies. In August 2015, a voucher was sold for \$350 million.

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1 We've also seen people like Martin Shkreli acquire drug companies
2 because those companies own a drug eligible for a Tropical Disease
3 Priority Review Voucher. In the case of Shkreli, his company then
4 announced that once the government awarded it a Priority Review
5 Voucher, they intended to make this lifesaving drug so expensive
6 that it would put it out of reach of almost all that need it.

7 This proves how profitable these vouchers are, and how easily
8 they can be exploited. Clearly, we need to be thoughtful in when
9 and how we award Priority Review Vouchers. I don't believe that
10 H.R. 3299, even with this amendment, frankly, which I do support,
11 takes the necessary steps to reform the existing Priority Review
12 Voucher Program. Instead, it creates an entire new incentive
13 program that we expect will have many of the very same problems.
14 I yield back.

15 The Chairman. The gentlelady's time is expired. Other
16 members wishing to speak on the amendment? The gentleman from --
17 Mr. Schrader. The gentleman is recognized for five minutes.

18 Mr. Schrader. Yes. I share some of the concerns of the
19 gentlelady from Illinois. And I'm a little concerned, or surprised
20 that the committee as a whole is not concerned about the open-ended
21 nature of the Priority Review process. I think the Voucher Program
22 is a good one. I think it has great value in tailored situations.
23 This bill, unfortunately, does not get to that. I think the
24 subcommittee that worked on this bill is a little outraged. The

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1 final bill does not represent anything that we worked on in the
2 subcommittee.

3 If this is truly regular order, I would hope that whether
4 you're Republican or Democrat, you want the process to reflect
5 the hard work of the subcommittee, and the members that are on
6 this thing.

7 The bill needs to be tailored. I mean, the reason, with all
8 due deference to the gentlelady from Indiana, the reason some of
9 these products aren't listed is there's already treatment for
10 them. Simple antibiotics take care of a lot of the drugs, excuse
11 me, the conditions that are on the list. For anthrax we also have
12 AVA vaccine, we've got anthrax immunoglobulin, smallpox we've got
13 MBA vaccine, botulism, we've got the antitoxin there. For
14 radionuclear stuff, potassium iodide, Neupogen, others, nerve
15 agent issues we've got midazolam. Do we want to continue to give
16 money to different companies, taxpayer money, when there's
17 already treatment available?

18 I think that a sunset is a good idea. That doesn't mean the
19 program goes away. If we think this program has value, we
20 reauthorize it. My colleagues on the other side of the aisle and
21 conservative Democrats like me, we'd like to reevaluate how we're
22 spending our money on our regular basis. And this is not what this
23 bill does. So I'm not opposed to Priority Review Vouchers. I mean,
24 I'm working on a bill with Mr. Bilirakis, one where there's no

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1 other agent, where Shkreli, whatever that guy's name is, you buy
2 up a company, you rip off the consumer and put people's health
3 at risk. That's not appropriate. That's where this program goes
4 to.

5 So I'm very concerned that, unfortunately, we're getting way
6 off of what the original Tropical Disease Program was about. We
7 need to set back, reevaluate, allow these programs to sunset and,
8 frankly, look at a bill that reflects what the subcommittee
9 actually tried to bring to the floor. I yield back.

10 Ms. DeGette. Will the gentleman yield?

11 Mr. Schrader. Yes, certainly.

12 Ms. DeGette. I just want to add, I agree. I actually think
13 that both of the sponsors on this bill have worked very hard, and
14 I also know that the Staffs have been trying to negotiate some
15 of these issues. And I want to associate myself with a lot of what
16 my colleagues on this side of the aisle have said about making
17 sure that we do this right, making sure that the PRV programs are
18 actually used in a targeted way.

19 I think that a sunset could be a really good idea to make
20 sure that happens. I've heard that at least 10, and as many as
21 20 years can be taken to develop these countermeasures, and so
22 I'm not -- frankly, this is just me speaking. I'm not sure a
23 seven-year period is the right amount. I know that Mr. Green is
24 going to offer Mrs. Capps' amendment for 12 years. I kind of feel

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1 like we're just throwing stuff up. I do think that a sunset period
2 would be good. I don't have the magic number of what that would
3 be. And I would hope since we're planning to go on recess this
4 week that we could -- irrespective of what happens, that we could
5 all work together over the August recess so when we bring this
6 bill to the floor, it's something that we can all support as a
7 committee, Democrats and Republicans, because I do think it's a
8 very bipartisan issue, and I think it's an important bill. And
9 I yield back to Mr. Schrader.

10 Mr. Schrader. I yield back my time, Mr. Chairman. Thank you.

11 The Chairman. The gentleman's time is expired. Other members
12 wishing to speak on the amendment? Oh, the gentlelady from
13 California has a unanimous consent request.

14
15 Ms. Eshoo. Mr. Chairman, I have a unanimous consent request
16 to place two letters -- -

17 The Chairman. Without objection.

18 Ms. Eshoo. -- that I failed to do earlier.

19 The Chairman. Thank you.

20 Now, are there other members wishing to speak on the
21 amendment? Seeing none, the vote is on the amendment. Gentleman
22 from New Jersey, roll call is requested. The Clerk will call the
23 tally.

24 The Clerk. Mr. Barton.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 [No response.]

2 The Clerk. Mr. Whitfield.

3 Mr. Whitfield. No.

4 The Clerk. Mr. Whitfield votes no.

5 Mr. Shimkus.

6 Mr. Shimkus. No.

7 The Clerk. Mr. Shimkus votes no.

8 Mr. Pitts.

9 Mr. Pitts. No.

10 The Clerk. Mr. Pitts votes no.

11 Mr. Walden.

12 Mr. Walden. No.

13 The Clerk. Mr. Walden votes no.

14 Mr. Murphy.

15 Mr. Murphy. No.

16 The Clerk. Mr. Murphy votes no.

17 Mr. Burgess.

18 Mr. Burgess. No.

19 The Clerk. Mr. Burgess votes no.

20 Mrs. Blackburn.

21 Mrs. Blackburn. No.

22 The Clerk. Mrs. Blackburn votes no.

23 Mr. Scalise.

24 Mr. Scalise. No.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. Mr. Scalise votes no.

2 Mr. Latta.

3 Mr. Latta. No.

4 The Clerk. Mr. Latta votes no.

5 Mrs. McMorris Rodgers.

6 [No response.]

7 The Clerk. Mr. Harper.

8 Mr. Harper. No.

9 The Clerk. Mr. Harper votes no.

10 Mr. Lance.

11 Mr. Lance. No.

12 The Clerk. Mr. Lance votes no.

13 Mr. Guthrie.

14 Mr. Guthrie. No.

15 The Clerk. Mr. Guthrie votes no.

16 Mr. Olson.

17 Mr. Olson. No.

18 The Clerk. Mr. Olson votes no.

19 Mr. McKinley.

20 Mr. McKinley. No.

21 The Clerk. Mr. McKinley votes no.

22 Mr. Pompeo.

23 Mr. Pompeo. No.

24 The Clerk. Mr. Pompeo votes no.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Kinzinger.

2 Mr. Kinzinger. No.

3 The Clerk. Mr. Kinzinger votes no.

4 Mr. Griffith.

5 Mr. Griffith. No.

6 The Clerk. Mr. Griffith votes no.

7 Mr. Bilirakis.

8 Mr. Bilirakis. No.

9 The Clerk. Mr. Bilirakis votes no.

10 Mr. Johnson.

11 Mr. Johnson. No.

12 The Clerk. Mr. Johnson votes no.

13 Mr. Long.

14 Mr. Long. No.

15 The Clerk. Mr. Long votes no.

16 Mrs. Ellmers.

17 Mrs. Ellmers. No.

18 The Clerk. Mrs. Ellmers votes no.

19 Mr. Bucshon.

20 Mr. Bucshon. No.

21 The Clerk. Mr. Bucshon votes no.

22 Mr. Flores.

23 Mr. Flores. No.

24 The Clerk. Mr. Flores votes no.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mrs. Brooks.

2 Mrs. Brooks. No.

3 The Clerk. Mrs. Brooks votes no.

4 Mr. Mullin.

5 Mr. Mullin. No.

6 The Clerk. Mr. Mullin votes no.

7 Mr. Hudson.

8 Mr. Hudson. No.

9 The Clerk. Mr. Hudson votes no.

10 Mr. Collins.

11 Mr. Collins. No.

12 The Clerk. Mr. Collins votes no.

13 Mr. Cramer.

14 Mr. Cramer. No.

15 The Clerk. Mr. Cramer votes no.

16 Mr. Pallone.

17 Mr. Pallone. Aye.

18 The Clerk. Mr. Pallone votes aye.

19 Mr. Rush.

20 Mr. Rush. Aye.

21 The Clerk. Mr. Rush votes aye.

22 Ms. Eshoo.

23 Ms. Eshoo. No.

24 The Clerk. Ms. Eshoo votes no.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Engel.

2 Mr. Engel. Aye.

3 The Clerk. Mr. Engel votes aye.

4 Mr. Green.

5 Mr. Green. Aye.

6 The Clerk. Mr. Green votes aye.

7 Ms. DeGette.

8 Ms. DeGette. No.

9 The Clerk. Ms. DeGette votes no.

10 Mrs. Capps.

11 [No response.]

12 The Clerk. Mr. Doyle.

13 Mr. Doyle. No.

14 The Clerk. Mr. Doyle votes no.

15 Ms. Schakowsky.

16 Ms. Schakowsky. Aye.

17 The Clerk. Ms. Schakowsky votes aye.

18 Mr. Butterfield.

19 Mr. Butterfield. No.

20 The Clerk. Mr. Butterfield votes no.

21 Ms. Matsui.

22 Ms. Matsui. No.

23 The Clerk. Ms. Matsui votes no.

24 Ms. Castor.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Ms. Castor. Aye.

2 The Clerk. Ms. Castor votes aye.

3 Mr. Sarbanes.

4 Mr. Sarbanes. Aye.

5 The Clerk. Mr. Sarbanes votes aye.

6 Mr. McNerney.

7 Mr. McNerney. No.

8 The Clerk. Mr. McNerney votes no.

9 Mr. Welch.

10 Mr. Welch. Aye.

11 The Clerk. Mr. Welch votes aye.

12 Mr. Lujan.

13 Mr. Lujan. No.

14 The Clerk. Mr. Lujan votes no.

15 Mr. Tonko.

16 Mr. Tonko. Aye.

17 The Clerk. Mr. Tonko votes aye.

18 Mr. Yarmuth.

19 Mr. Yarmuth. Aye.

20 The Clerk. Mr. Yarmuth votes aye.

21 Ms. Clarke.

22 Ms. Clarke. Aye.

23 The Clerk. Ms. Clarke votes aye.

24 Mr. Loeb sack.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Loeb sack. Aye.

2 The Clerk. Mr. Loeb sack votes aye.

3 Mr. Schrader.

4 Mr. Schrader. Aye.

5 The Clerk. Mr. Schrader votes aye.

6 Mr. Kennedy.

7 Mr. Kennedy. Aye.

8 The Clerk. Mr. Kennedy votes aye.

9 Mr. Cardenas.

10 Mr. Cardenas. No.

11 The Clerk. Mr. Cardenas votes no.

12 Chairman Upton.

13 Chairman Upton. Votes no.

14 The Clerk. Chairman Upton votes no.

15 The Chairman. Other members wishing to cast a vote? Mr.
16 Barton.

17 Mr. Barton. No.

18 The Clerk. Mr. Barton votes no.

19 The Chairman. Any other members wishing to change their vote
20 or cast a vote? Seeing none, the Clerk will report the tally.

21 The Clerk. Mr. Chairman, on that vote there were 14 ayes,
22 38 nos.

23 The Chairman. Fourteen ayes, 38 nos, the amendment is not
24 agreed to.

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1 Are there further amendments to the bill? The gentleman from
2 Texas, Mr. Green, has an amendment at the desk.

3 Mr. Green. There is an amendment at the desk, Mr. Chairman,
4 that I agreed to carry for colleague, Mrs. Capps, who's on the
5 floor of the House.

6 The Chairman. The Clerk will report the title of the
7 amendment.

8 [The Amendment offered by Mrs. Capps follows:]

9

10 *****INSERT 19*****

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1 The Clerk. Amendment to the amendment in the nature of a
2 substitute to H.R. 3299 offered by Mr. Green for Mrs. Capps.

3 The Chairman. And the amendment will be considered as read.
4 The Staff will distribute the amendment, and the gentleman is
5 given five minutes in support of the amendment.

6 Mr. Green. Thank you, Mr. Chairman.

7 I appreciate what the authors of the legislation are trying
8 to achieve with H.R. 3299, but I also understand the concerns
9 raised by the Ranking Member, the FDA, and others on our committee
10 about the effectiveness and utility of Priority Review Vouchers.
11 Priority Review Vouchers particularly heighten when you consider
12 that the program being created by this bill would be a permanent
13 program, and that there are also concerns that the language may
14 not be tight enough to insure that the products moved through this
15 pathway will actually meet the needs of the federal government.

16 The truth is, if the jury is still out on the effectiveness
17 of the PRV Programs as a whole. There's great debate as to whether
18 PRV Programs are effective at getting treatments to those who need
19 them, or that they truly incentivize new investment in these
20 areas.

21 As we have seen in the Tropical Disease Program, PRV Program,
22 sometimes there's novel pathways with unintended consequences and
23 loopholes that we need to have the chance to address. Given that
24 medical countermeasures are products developed for purchase by

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1 the federal government it is critical that the program works the
2 way it was intended to so that we get the products we need, and
3 the taxpayers aren't on the hook for those we don't.

4 As such, I do believe it's important that we be required to
5 revisit this program down the road, if it becomes law. Some offered
6 a seven-year time frame, that wasn't enough to gather all the data.
7 Others have proposed 17 years, but that may be too long a window
8 to insure the problems are addressed because the taxpayers on the
9 hook. This amendment splits the difference and would sunset the
10 program after 12 years. And, you know, Congress can always revisit
11 it, but it would insure transparency by ordering a preliminary
12 GAO report to be made available every seven years, while a more
13 thorough report is released a year before the reauthorization.

14 It's important to note that nothing in the amendment would
15 preclude Congress from reauthorizing the program beyond the
16 12-year window. What it would do is to insure that Congress review
17 the MCM PRV Program after more information on the effectiveness
18 of this and the other PRV Programs are available. And it would
19 provide a time frame for addressing any potential unintended
20 consequences or loopholes that are found in the program once it's
21 operational. And I recognize that some may think it's too long
22 enough, but other think it's too long a window, but this important
23 amount of time should be sufficient to gauge the workings of the
24 program, as well as get data from the other existing PRV Programs

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1 to help inform Congress for reauthorization.

2 This amendment, I think, is a commonsense addition to this
3 legislation, and I urge my colleagues to support it. And I'll yield
4 back my time.

5 The Chairman. The gentleman yields back in an effort to save
6 time, and I'll yield myself to strike the last word. We don't
7 support the sunset after 10 years, and I would urge my colleagues,
8 12. They don't support 10, either; 12 years. And I would urge my
9 Republican colleagues and Democrat colleagues to vote no, and I'll
10 yield back.

11 Other members wishing to speak on the amendment? The
12 gentleman from New Jersey, five minutes.

13 Mr. Pallone. Thank you, Mr. Chairman.

14 As I stated previously, Congress found it appropriate to
15 sunset programs intended to incentivize development of drugs to
16 treat children so that we have the opportunity to evaluate whether
17 an incentive program we created worked. And I fail to understand
18 how we justify a different approach in the medical countermeasure
19 space, and how an opportunity to evaluate if a program is
20 successful before permanently authorizing it is not sound
21 governance.

22 The Best Pharmaceuticals for Children Act, and the Pediatric
23 Research Equity Act, which offered additional exclusivity to drug
24 manufacturers who conduct Pediatric studies were initially

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1 enacted for five years. Both programs were reauthorized for an
2 additional five years multiple times before we made the programs
3 permanent in 2012. And these sunset dates allowed us to evaluate
4 the effectiveness of these programs as an incentive,
5 understanding the impact on the FDA and understanding if the
6 benefits of the program are worth the cost to the American people.

7 We also included an initial cap and later a sunset for the
8 Rare Pediatric PRV Program. The GAO study of this program, the
9 only study to date of any PRV program, found little evidence that
10 the program was incentivizing new investment in drug research and
11 development to treat Rare Pediatric Diseases. Given the lack of
12 understanding about whether PRV Programs are incentivizing new
13 investment versus serving as a windfall to drug manufacturers
14 already developing, I strongly urge my colleagues to consider if
15 a permanent program is sensible policy.

16 While a 12-year sunset is longer than I believe necessary,
17 I support this amendment. It will prevent an unproven program from
18 being enacted permanently without evidence that it works. A
19 12-year sunset will allow us to assess if the medical
20 countermeasures PRV Program is effective, and if there are
21 unintended consequences before permanently authorizing a program
22 that gives such a valuable award to drug companies at the expense
23 of FDA's ability to expedite review of other important drugs to
24 the American people. I yield back.

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1 The Chairman. Other members wishing to speak? The gentlelady
2 from California is recognized.

3 Ms. Eshoo. Thank you, Mr. Chairman. I move to strike the last
4 word.

5 First, I want to thank the Ranking Member for talking about
6 and mentioning the two laws, bills I both wrote, the Better
7 Pharmaceutical for Children's Act, as well as the other
8 legislation. The difference between those and the Priority Review
9 mechanisms that are in the laws that Mr. Pallone just raised, and
10 I wrote, is that those -- the drugs that we're talking about in
11 this program are not marketed. In the Children's Pediatric bill,
12 the Better Pharmaceutical Act bill, it's a different story for
13 those. So I think that there is a big difference between the two,
14 and I think members need to understand that and have an
15 appreciation of it.

16 On the language that's in the amendment, the 15 years was
17 structured in the following way. In the legislation that
18 Congresswoman Brooks and I are sponsoring, you know that we called
19 for the GAO study. That GAO study comes out in 16 years from the
20 enactment of the bill, and that's why 15 was in the bill, because
21 of the GAO study. So just so that you understand that there's a
22 linkage, and that we're consistent about what we're doing. Some
23 like it, some don't, but that's the reason for it. And I yield
24 back the balance of my time.

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1 The Chairman. The gentlelady yields back. Other members
2 wishing to speak on the amendment? Seeing none -- a recorded vote
3 is asked for. Note votes have started on the House floor so we
4 will hurry this roll call.

5 The Clerk. Mr. Barton.

6 Mr. Barton. No.

7 The Clerk. Mr. Barton votes no.

8 Mr. Whitfield.

9 Mr. Whitfield. No.

10 The Clerk. Mr. Whitfield votes no.

11 Mr. Shimkus.

12 Mr. Shimkus. No.

13 The Clerk. Mr. Shimkus votes no.

14 Mr. Pitts.

15 Mr. Pitts. No.

16 The Clerk. Mr. Pitts votes no.

17 Mr. Walden.

18 Mr. Walden. No.

19 The Clerk. Mr. Walden votes no.

20 Mr. Murphy.

21 Mr. Murphy. No.

22 The Clerk. Mr. Murphy votes no.

23 Mr. Burgess.

24 Mr. Burgess. No.

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1 The Clerk. Mr. Burgess votes no.

2 Mrs. Blackburn.

3 Mrs. Blackburn. No.

4 The Clerk. Mrs. Blackburn votes no.

5 Mr. Scalise.

6 [No response.]

7 The Clerk. Mr. Latta.

8 Mr. Latta. No.

9 The Clerk. Mr. Latta votes no.

10 Mrs. McMorris Rodgers.

11 [No response.]

12 The Clerk. Mr. Harper.

13 Mr. Harper. No.

14 The Clerk. Mr. Harper votes no.

15 Mr. Lance.

16 Mr. Lance. No.

17 The Clerk. Mr. Lance votes no.

18 Mr. Guthrie.

19 Mr. Guthrie. No.

20 The Clerk. Mr. Guthrie votes no.

21 Mr. Olson.

22 Mr. Olson. No.

23 The Clerk. Mr. Olson votes no.

24 Mr. McKinley.

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1 Mr. McKinley. No.

2 The Clerk. Mr. McKinley votes no.

3 Mr. Pompeo.

4 Mr. Pompeo. No.

5 The Clerk. Mr. Pompeo votes no.

6 Mr. Kinzinger.

7 Mr. Kinzinger. No.

8 The Clerk. Mr. Kinzinger votes no.

9 Mr. Griffith.

10 Mr. Griffith. No.

11 The Clerk. Mr. Griffith votes no.

12 Mr. Bilirakis.

13 Mr. Bilirakis. No.

14 The Clerk. Mr. Bilirakis votes no.

15 Mr. Johnson.

16 Mr. Johnson. No.

17 The Clerk. Mr. Johnson votes no.

18 Mr. Long.

19 Mr. Long. No.

20 The Clerk. Mr. Long votes no.

21 Mrs. Ellmers.

22 Mrs. Ellmers. No.

23 The Clerk. Mrs. Ellmers votes no.

24 Mr. Bucshon.

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1 Mr. Bucshon. No.

2 The Clerk. Mr. Bucshon votes no.

3 Mr. Flores.

4 Mr. Flores. No.

5 The Clerk. Mr. Flores votes no.

6 Mrs. Brooks.

7 Mrs. Brooks. No.

8 The Clerk. Mrs. Brooks votes no.

9 Mr. Mullin.

10 Mr. Mullin. No.

11 The Clerk. Mr. Mullin votes no.

12 Mr. Hudson.

13 Mr. Hudson. No.

14 The Clerk. Mr. Hudson votes no.

15 Mr. Collins.

16 Mr. Collins. No.

17 The Clerk. Mr. Collins votes no.

18 Mr. Cramer.

19 Mr. Cramer. No.

20 The Clerk. Mr. Cramer votes no.

21 Mr. Pallone.

22 Mr. Pallone. Aye.

23 The Clerk. Mr. Pallone votes aye.

24 Mr. Rush.

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1 Mr. Rush. Aye.

2 The Clerk. Mr. Rush votes aye.

3 Ms. Eshoo.

4 Ms. Eshoo. No.

5 The Clerk. Ms. Eshoo votes no.

6 Mr. Engel.

7 Mr. Engel. Aye.

8 The Clerk. Mr. Engel votes aye.

9 Mr. Green.

10 Mr. Green. Aye.

11 The Clerk. Mr. Green votes aye.

12 Ms. DeGette.

13 Ms. DeGette. Aye.

14 The Clerk. Ms. DeGette votes aye.

15 Mrs. Capps.

16 [No response.]

17 The Clerk. Mr. Doyle.

18 Mr. Doyle. Aye.

19 The Clerk. Mr. Doyle votes aye.

20 Ms. Schakowsky.

21 Ms. Schakowsky. Yes.

22 The Clerk. Ms. Schakowsky votes aye.

23 Mr. Butterfield.

24 Mr. Butterfield. No.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. Mr. Butterfield votes no.

2 Ms. Matsui.

3 Ms. Matsui. No.

4 The Clerk. Ms. Matsui votes no.

5 Ms. Castor.

6 Ms. Castor. No.

7 The Clerk. Ms. Castor votes no.

8 Mr. Sarbanes.

9 Mr. Sarbanes. Aye.

10 The Clerk. Mr. Sarbanes votes aye.

11 Mr. McNerney.

12 Mr. McNerney. Aye.

13 The Clerk. Mr. McNerney votes aye.

14 Mr. Welch.

15 Mr. Welch. Aye.

16 The Clerk. Mr. Welch votes aye.

17 Mr. Lujan.

18 Mr. Lujan. Aye.

19 The Clerk. Mr. Lujan votes aye.

20 Mr. Tonko.

21 Mr. Tonko. Aye.

22 The Clerk. Mr. Tonko votes aye.

23 Mr. Yarmuth.

24 Mr. Yarmuth. Aye.

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1 The Clerk. Mr. Yarmuth votes aye.

2 Ms. Clarke.

3 Ms. Clarke. Aye.

4 The Clerk. Ms. Clarke votes aye.

5 Mr. Loeb sack.

6 Mr. Loeb sack. Aye.

7 The Clerk. Mr. Loeb sack votes aye.

8 Mr. Schrader.

9 Mr. Schrader. Aye.

10 The Clerk. Mr. Schrader votes aye.

11 Mr. Kennedy.

12 Mr. Kennedy. Aye.

13 The Clerk. Mr. Kennedy votes aye.

14 Mr. Cardenas.

15 Mr. Cardenas. No.

16 The Clerk. Mr. Cardenas votes no.

17 Chairman Upton.

18 Chairman Upton. Votes no.

19 The Clerk. Chairman Upton votes no.

20 The Chairman. Those wishing to vote, change your vote? Seeing
21 none, the Clerk will report the tally.

22 The Clerk. Mr. Chairman, on that vote there were 18 ayes,
23 34 nos.

24 The Chairman. Seventeen ayes, 24 nos, the amendment is not

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1 agreed to.

2 Are there further amendments to the bill? Seeing none, the
3 vote occurs on final passage. Roll call is requested. Tell the
4 members we'll come back tomorrow for the last bill at 10:00
5 tomorrow. So the Clerk will call the tally for final passage.

6 The Clerk. Mr. Barton.

7 Mr. Barton. Aye.

8 The Clerk. Mr. Baton votes aye.

9 Mr. Whitfield.

10 Mr. Whitfield. Aye.

11 The Clerk. Mr. Whitfield votes aye.

12 Mr. Shimkus.

13 Mr. Shimkus. Aye.

14 The Clerk. Mr. Shimkus votes aye.

15 Mr. Pitts.

16 Mr. Pitts. Aye.

17 The Clerk. Mr. Pitts votes aye.

18 Mr. Walden.

19 Mr. Walden. Aye.

20 The Clerk. Mr. Walden votes aye.

21 Mr. Murphy.

22 Mr. Murphy. Aye.

23 The Clerk. Mr. Murphy votes aye.

24 Mr. Burgess.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Burgess. Aye.

2 The Clerk. Mr. Burgess votes aye.

3 Mrs. Blackburn.

4 Mrs. Blackburn. Aye.

5 The Clerk. Mrs. Blackburn votes aye.

6 Mr. Scalise.

7 [No response.]

8 The Clerk. Mr. Latta.

9 Mr. Latta. Aye.

10 The Clerk. Mr. Latta votes aye.

11 Mrs. McMorris Rodgers.

12 [No response.]

13 The Clerk. Mr. Harper.

14 Mr. Harper. Aye.

15 The Clerk. Mr. Harper votes aye.

16 Mr. Lance.

17 Mr. Lance. Aye.

18 The Clerk. Mr. Lance votes aye.

19 Mr. Guthrie.

20 Mr. Guthrie. Aye.

21 The Clerk. Mr. Guthrie votes aye.

22 Mr. Olson.

23 Mr. Olson. Aye.

24 The Clerk. Mr. Olson votes aye.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. McKinley.

2 Mr. McKinley. Aye.

3 The Clerk. Mr. McKinley votes aye.

4 Mr. Pompeo.

5 Mr. Pompeo. Aye.

6 The Clerk. Mr. Pompeo votes aye.

7 Mr. Kinzinger.

8 Mr. Kinzinger. Aye.

9 The Clerk. Mr. Kinzinger votes aye.

10 Mr. Griffith.

11 Mr. Griffith. Aye.

12 The Clerk. Mr. Griffith votes aye.

13 Mr. Bilirakis.

14 Mr. Bilirakis. Aye.

15 The Clerk. Mr. Bilirakis votes aye.

16 Mr. Johnson.

17 Mr. Johnson. Aye.

18 The Clerk. Mr. Johnson votes aye.

19 Mr. Long.

20 Mr. Long. Aye.

21 The Clerk. Mr. Long votes aye.

22 Mrs. Ellmers.

23 Mrs. Ellmers. Aye.

24 The Clerk. Mrs. Ellmers votes aye.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Bucshon.

2 Mr. Bucshon. Aye.

3 The Clerk. Mr. Bucshon votes aye.

4 Mr. Flores.

5 Mr. Flores. Aye.

6 The Clerk. Mr. Flores votes aye.

7 Mrs. Brooks.

8 Mrs. Brooks. Aye.

9 The Clerk. Mrs. Brooks votes aye.

10 Mr. Mullin.

11 Mr. Mullin. Aye.

12 The Clerk. Mr. Mullin votes aye.

13 Mr. Hudson.

14 Mr. Hudson. Aye.

15 The Clerk. Mr. Hudson votes aye.

16 Mr. Collins.

17 Mr. Collins. Aye.

18 The Clerk. Mr. Collins votes aye.

19 Mr. Cramer.

20 Mr. Cramer. Aye.

21 The Clerk. Mr. Cramer votes aye.

22 Mr. Pallone.

23 Mr. Pallone. No.

24 The Clerk. Mr. Pallone votes no.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Rush.

2 Mr. Rush. No.

3 The Clerk. Mr. Rush votes no.

4 Ms. Eshoo.

5 Ms. Eshoo. Aye.

6 The Clerk. Ms. Eshoo votes aye.

7 Mr. Engel.

8 Mr. Engel. Aye.

9 The Clerk. Mr. Engel votes aye.

10 Mr. Green.

11 Mr. Green. No.

12 The Clerk. Mr. Green votes no.

13 Ms. DeGette.

14 Ms. DeGette. No.

15 The Clerk. Ms. DeGette votes no.

16 Mrs. Capps.

17 [No response.]

18 The Clerk. Mr. Doyle.

19 Mr. Doyle. Aye.

20 The Clerk. Mr. Doyle votes aye.

21 Ms. Schakowsky.

22 Ms. Schakowsky. No.

23 The Clerk. Ms. Schakowsky votes no.

24 Mr. Butterfield.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Butterfield. Aye.

2 The Clerk. Mr. Butterfield votes aye.

3 Ms. Matsui.

4 Ms. Matsui. Aye.

5 The Clerk. Ms. Matsui votes aye.

6 Ms. Castor.

7 Ms. Castor. No.

8 The Clerk. Ms. Castor votes no.

9 Mr. Sarbanes.

10 Mr. Sarbanes. No.

11 The Clerk. Mr. Sarbanes votes no.

12 Mr. McNerney.

13 Mr. McNerney. Aye.

14 The Clerk. Mr. McNerney votes aye.

15 Mr. Welch.

16 Mr. Welch. No.

17 The Clerk. Mr. Welch votes no.

18 Mr. Lujan.

19 Mr. Lujan. No.

20 The Clerk. Mr. Lujan votes no.

21 Mr. Tonko.

22 Mr. Tonko. No.

23 The Clerk. Mr. Tonko votes no.

24 Mr. Yarmuth.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Yarmuth. No.

2 The Clerk. Mr. Yarmuth votes no.

3 Ms. Clarke.

4 Ms. Clarke. No.

5 The Clerk. Ms. Clarke votes no.

6 Mr. Loeb sack.

7 Mr. Loeb sack. No.

8 The Clerk. Mr. Loeb sack votes no.

9 Mr. Schrader.

10 Mr. Schrader. No.

11 The Clerk. Mr. Schrader votes no.

12 Mr. Kennedy.

13 Mr. Kennedy. No.

14 The Clerk. Mr. Kennedy votes no.

15 Mr. Cardenas.

16 Mr. Cardenas. Aye.

17 The Clerk. Mr. Cardenas votes aye.

18 Chairman Upton.

19 Chairman Upton. Votes aye.

20 The Clerk. Chairman Upton votes aye.

21 The Chairman. Other members wishing to change your vote, or
22 cast a vote? Seeing none, the Clerk will report the tally.

23 The Clerk. Mr. Chairman, on that vote there were 36 ayes,
24 and 15 nos.

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1 The Chairman. Thirty-six ayes, 15 nos, the bill as amended
2 is passed, and the committee stands in recess until 10:00
3 tomorrow.

4 [Whereupon, at 9:29 p.m., the committee was adjourned.]

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1 NEAL R. GROSS & CO., INC.

2 RPTS MORRISON

3 HIF195000

4

5

6 MARKUP OF:

7 H.R. 5510, FTC PROCESS AND TRANSPARENCY

8 REFORM ACT OF 2016;

9 H.R. 5111, CONSUMER REVIEW FAIRNESS ACT;

10 H.R. 5092, REINFORCING AMERICAN MADE

11 PRODUCTS ACT;

12 H.R. 5104, BETTER ONLINE TICKET SALES

13 (BOTS) ACT;

14 H.R. 1301, AMATEUR RADIO PARITY ACT OF 2015,

15 AND AN AMENDMENT IN THE NATURE OF A

16 SUBSTITUTE TO H.R. 130;

17 HR 3299, STRENGTHENING PUBLIC HEALTH

18 EMERGENCY RESPONSE ACT OF 2015;

19 H.R. 921, SPORTS MEDICINE LICENSURE CLARITY

20 ACT OF 2015; AND,

21 H.R. 670, SPECIAL NEEDS TRUST FAIRNESS ACT

22 OF 2015.

23 WEDNESDAY, JULY 13, 2016

24 House of Representatives

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Committee on Energy and Commerce

2 Washington, D.C.

3

4

5

6 The committee met, pursuant to call, at 4:00 p.m., in Room
7 2123 Rayburn House Office Building, Hon. Fred Upton [chairman of
8 the committee] presiding.

9 Members present: Representatives Upton, Barton, Whitfield,
10 Shimkus, Pitts, Walden, Murphy, Burgess, Blackburn, Scalise,
11 Latta, McMorris Rodgers, Harper, Lance, Guthrie, Olson, McKinley,
12 Kinzinger, Griffith, Bilirakis, Johnson, Long, Ellmers, Bucshon,
13 Flores, Brooks, Mullin, Hudson, Collins, Cramer, Pallone, Rush,
14 Eshoo, Green, DeGette, Capps, Doyle, Schakowsky, Butterfield,
15 Matsui, Castor, Sarbanes, McNerney, Welch, Lujan, Tonko, Yarmuth,
16 Clarke, Loeb sack, Schrader, Kennedy, and Cardenas.

17

18 Staff present: Gary Andres, Staff Director; Will Batson,
19 Legislative Clerk, Energy and Power; Mike Bloomquist, Deputy
20 Staff Director; Sean Bonyun, Communications Director; Elena
21 Brennan, Staff Assistant; Rebecca Card, Assistant Press
22 Secretary; Karen Christian, General Counsel; James Decker, Policy
23 Coordinator, Commerce, Manufacturing, and Trade; Paige Decker,
24 Executive Assistant; Graham Dufault, Counsel, Commerce,

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1 Manufacturing, and Trade; Paul Edattel, Chief Counsel, Health;
2 Melissa Froelich, Counsel, Commerce, Manufacturing, and Trade;
3 Giulia Giannangeli, Legislative Clerk, Commerce, Manufacturing,
4 and Trade; Jay Gulshen, Staff Assistant; A.T. Johnston, Senior
5 Policy Advisor; Peter Kielty, Deputy General Counsel; Carly
6 McWilliams, Professional Staff Member, Health; Paul Nagle, Chief
7 Counsel, Commerce, Manufacturing, and Trade; Tim Pataki,
8 Professional Staff Member; Graham Pittman, Legislative Clerk;
9 Mark Ratner, Policy Advisor to the Chairman; David Redl, Chief
10 Counsel, Telecom; Michelle Rosenberg, GAO Detailee, Health; Chris
11 Santini, Policy Coordinator, Oversight and Investigations; Dan
12 Schneider, Press Secretary; Olivia Trusty, Professional Staff,
13 Commerce, Manufacturing, and Trade; Dylan Vorbach, Deputy Press
14 Secretary; Gregory Watson, Legislative Clerk, Communications and
15 Technology; Michelle Ash, Minority Chief Counsel, Commerce,
16 Manufacturing, and Trade; Jen Berenholz, Minority Chief Clerk;
17 Jeff Carroll, Minority Staff Director; Elizabeth Ertel, Minority
18 Deputy Clerk; David Goldman, Minority Chief Counsel,
19 Communications and Technology; Lisa Goldman, Minority Counsel;
20 Waverly Gordon, Minority Professional Staff Member; Tiffany
21 Guarascio, Minority Deputy Staff Director and Chief Health
22 Advisor; Jerry Leverich, Minority Counsel; Dan Miller, Minority
23 Staff Assistant; Caroline Paris-Behr, Minority Policy Analyst;
24 Rachel Pryor, Minority Health Policy Advisor; Tim Robinson,

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1 Minority Chief Counsel; Samantha Satchell, Minority Policy
2 Analyst; Matt Schumacher, Minority Press Assistant; Ryan
3 Skukowski, Minority Senior Policy Analyst; Andrew Souvall,
4 Minority Director of Communications, Outreach and Member
5 Services; Kimberlee Trzeciak, Minority Health Policy Advisor; and
6 Megan Velez, Minority FDA Detailee.

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1 The Chairman. The meeting will come to order. So I want
2 members and folks watching to know sort of what the agenda is.
3 We delayed this Markup because of a Bill on the floor. That Bill
4 is almost done. They're in the motion to recommit. It's going to
5 be a little while before votes are called on the floor, so we'll
6 work until those votes are called, which we'll recess until after
7 the votes are done. And immediately following the recorded votes
8 on the House floor we'll come back to continue the Markup, but
9 we will hold or roll, I guess you could say, roll the votes ordered
10 between that point and 8:00 p.m. so that people can do dinner,
11 whatever they've got planned. And at 8:00 we will then have a call
12 of the roll on the votes ordered at that point, and we will
13 continue. And since we're going to be in until midnight or 1:00,
14 it's my understanding on the floor, we'll continue so that we don't
15 have to be here tomorrow in the Markup, assuming that we get done
16 by then, which I think we can. If I had to guess, I don't think
17 we'll be in maybe past 9:00 or 10:00 on the Bills that we've got
18 going, and maybe that will cause some of the things to move a little
19 bit faster.

20 So that's the agenda, so you're free not to be here, but
21 knowing that votes will be called at 8:00 on those amendments or
22 Bills that a vote is asked -- a recorded vote is asked for. So,
23 the Chair would first call up H.R. 1301, and ask the Clerk to
24 report.

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1

[The Bill H.R. 1301 follows:]

2

3

*****INSERT 1*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 1301, to direct the Federal Communications
2 Commission to extend to private land use restrictions its rule
3 relating to reasonable accommodation of amateur service
4 communications.

5 The Chairman. And without objection the first reading of the
6 Bill is dispensed with. The Bill will be open for amendment at
7 any point.

8 The Chair would recognize Mr. Walden.

9 Mr. Walden. Thank you, Mr. Chairman. I have a --

10 The Chairman. Offering an amendment in the nature of a
11 substitute?

12 Mr. Walden. I have an amendment in the nature of a substitute,
13 yes.

14 Mr. Smith. And the Clerk will report the title of the
15 amendment.

16 The Clerk. Amendment in the nature of a substitute to H.R.
17 1301 offered by Mr. Walden.

18 [The Amendment offered by Mr. Walden follows:]

19

20 *****INSERT 2*****

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1 The Chairman. And without objection the reading of the
2 amendment is dispensed with, and the gentleman is -- Staff will
3 distribute the amendment, and the gentleman is recognized for five
4 minutes in support of his amendment.

5 Mr. Walden. I thank the Chairman, and I want to thank Ms.
6 Eshoo and her team, our team, Mr. Kinzinger's team, everybody has
7 worked together on this, and I'll talk more about that in the
8 future. But we offer this as, in effect, a joint amendment, a
9 bipartisan effort here.

10 There are about 730,000 amateur radio operators in the United
11 States. I should know, I'm actually one of them. The rest of you
12 all pretend to be hams, but I'm actually a licensed one. Amateur
13 radio operators utilize a variety of radio frequencies to
14 communicate across town, across the country, around the world,
15 and even into outer space. Amateur radio operators also occupy
16 an important role in the emergency response system. They are often
17 able to establish communications during natural disasters when
18 commercial networks are unavailable.

19 Unfortunately, Mr. Chairman, the law doesn't afford amateur
20 radio operations the same level of freedom to operate that are
21 enjoyed by consumers of other radio services. For example, the
22 FCC's regulations ensure consumer's access to direct broadcast
23 satellite services. You can have a satellite dish. H.R. 1301 seeks
24 to provide hams with the certainty that like DBS satellite

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1 customers, they will be able to enjoy access to communication
2 service of their choice regardless of where they live.

3 This Bill has come a long way since it was first introduced.
4 Proud to say that thanks to the hard work of our Staff and members
5 of the amateur radio and community association communities today
6 H.R. 1301 enjoys broad support with this manager's amendment. This
7 bipartisan amendment in the nature of a substitute represents
8 months of meetings, hard work, compromise to ensure the amateurs
9 are protected but not at the expense of the rights of Americans
10 living in deed-restricted communities. We found a good balance
11 here.

12 The amendment guarantees that even in deed-restricted
13 communities, amateur radio operators are able to use an effective
14 outdoor antenna. Without an effective antenna, amateur radio
15 operators are severely limited, so this amendment ensures that
16 amateurs are free to pursue their passion wherever they live.

17 This amendment also respects, though, the rights of
18 Americans, including amateur radio operators who have chosen to
19 live in deed-restricted communities. Millions of Americans live
20 in communities like these, and choose to set their own esthetic
21 and other rules. This is a knowing choice, and must be respected.
22 This amendment does just that. While it's rare to have the two
23 groups with opposing viewpoints walk away from legislation happy,
24 by golly, I think we've done it here.

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1 Both the Amateur Radio Relay League, that's the Association
2 of HAM Radio Operators, and the Community Association Institute
3 that represents the nation's community associations have written
4 us letters to the subcommittee in support of this amendment.

5 So again, I'd like to thank our Staff, the Staff of Mr.
6 Kinzinger, the Ranking Member Ms. Eshoo, the Amateur Radio Relay
7 League, the Community Associations Institute all for their hard
8 work and expertise which allows us to move forward with this
9 legislation. Compromise memorialized in our amendment in the
10 nature of substitute represents the best of what our committee
11 can do when we work together, bipartisan compromise that meets
12 the needs of all parties involved. I thank my colleagues and urge
13 you to support this amendment in the nature of a substitute. And
14 I'd yield to my friend and colleague from California, if she would
15 like to do it that way, Ms. Eshoo, for comments on our joint
16 amendment.

17 Ms. Eshoo. I thank the gentleman. I'm glad that we've come
18 to an agreement on this Bill. When we originally considered it
19 in the subcommittee, I was worried that it would violate the rights
20 of homeowners associations, and Chairman Walden assured me that
21 he would work with me to address the concerns before the Bill was
22 marked up by the Full Committee, and he did. So we found a balance
23 that works for all of the stakeholders, and the Bill is now
24 supported by the Community Associations Institute, and the

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1 Amateur Radio Relay League. So I guess when you have both of those
2 groups as the bookends of the effort, you know that it's been
3 worked out. So I thank Mr. Walden, I thank Mr. Kinzinger, and I
4 recommend to all of our colleagues, both sides of the aisle, that
5 they support it. It's a good Bill, it's a good worked-out Bill.

6 Mr. Walden. And with that, I'd yield -- -

7 Ms. Eshoo. Thank you.

8 Mr. Walden. -- to the gentleman from Illinois, Mr.
9 Kinzinger, for comments.

10 Mr. Kinzinger. Well, thank you, Mr. Chair. I just want to
11 thank the Ranking Member, I want to thank you, Chairman Upton,
12 Staff, everybody for working together on this for the associations
13 involved. This is a good amendment, strikes the right balance,
14 and just goes to show how legislating may take a little hard work,
15 but we can always ultimately get there. So I thank you, and I yield
16 back to you.

17 Mr. Walden. And in the nature of returning time to the
18 committee to move forward on our other business, I yield back with
19 10 seconds left.

20 The Chairman. The gentleman yields back. Other members
21 wishing to speak? Seeing none, the vote occurs on the amendment
22 in the nature of a substitute. All those in favor say aye.

23 [A chorus of ayes]

24 The Chairman. Those opposed say no. The ayes have it, the

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1 ayes have it. Amendment in the nature of a substitute is agreed
2 to.

3 Are there further amendments to the Bill? Seeing none, the
4 question now occurs on favorably reporting H.R. 1301 as amended
5 to the House. All those in favor so signify by saying aye.

6 [Chorus of ayes]

7 The Chairman. Those opposed say no. The ayes appear to have
8 it, the ayes have it, and the Bill is favorably reported.

9 The Chair would now call up H.R.5111 and ask the Clerk to
10 report.

11 [The Bill H.R. 5111 follows:]

12

13 *****INSERT 3*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 5111, to prohibit the use of certain clauses
2 and form contracts that restrict the ability of a consumer to
3 communicate regarding the goods or services offered in interstate
4 commerce that were the subject of the contract and for other
5 purposes.

6 The Chairman. And without objection the first reading of the
7 Bill is dispensed with. The Bill will be open for amendment at
8 any point. The Staff -- oh, the Bill has been called up, and are
9 there any bipartisan amendments to the Bill? Are there any
10 amendments to the Bill?

11 Mr. Burgess has an amendment at the desk.

12 [The Amendment offered by Mr. Burgess follows:]

13

14 *****INSERT 4*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Burgess. Yes, Mr. Chairman. This -- -

2 The Chairman. And the Staff -- the Clerk will report the title
3 of the amendment.

4 The Clerk. Amendment to H.R. 5111 offered by Mr. Burgess.

5 The Chairman. And the amendment will be considered as read.

6 The Staff will distribute the amendment, and the gentleman is
7 recognized for five minutes in support of his amendment.

8 Mr. Burgess. Thanks, Mr. Chairman. The amendment would add
9 a savings clause to the Consumer Review Fairness Act clarifying
10 that the provisions of the Act do not supersede or impair the FTC
11 Act, or other federal laws. The Federal Trade Commission suggested
12 we include such a savings clause, and we are happy we've been able
13 to accommodate this in a bipartisan way.

14 We also add "is," after "or," in a provision of the Rule of
15 Construction. This corrects a drafting issue where the
16 second-half of the sentence could be read as modifying the
17 first-half of the sentence, a reading that was clearly not
18 intended by the drafters. With these small changes we can move
19 forward and encourage support from both sides of the dias. I yield
20 back.

21 The Chairman. The gentleman yields back. Other members
22 wishing to speak on the amendment? The gentleman from
23 Massachusetts, Mr. Kennedy, is recognized for five minutes.

24 Mr. Kennedy. Thank you, Mr. Chairman. Move to strike the last

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1 word.

2 Mr. Chairman, I want to thank you for bringing this Bill to
3 a Markup. I'm pleased to say that we engaged in good faith
4 discussions over the past month, and I sincerely appreciate the
5 work on both the Minority and Majority Staff, as well as some
6 outside groups that were working on this issue.

7 We all agree that form contracts containing non-disparaging
8 clauses in their terms of service are simply unacceptable. Just
9 like posing a positive experience, consumers have an undeniable
10 right to voice their honest concerns when they experience fails
11 to meet those expectations.

12 This amendment is a technical addition to insuring the
13 language of the Bill does not limit, impair, or supersede the
14 operation of the Federal Trade Commission. I ask my colleagues
15 to support this amendment and the underlying Bill, and I yield
16 back the balance of my time.

17 The Chairman. The gentleman yields back. Other members
18 wishing to speak on the amendment? Seeing none, the vote occurs
19 on the amendment offered by the gentleman from Texas, Mr. Burgess.
20 All those in favor say aye.

21 [A chorus of ayes]

22 The Chairman. Those opposed say no. The ayes appear to have
23 it, the ayes have it, and the amendment is agreed to. Are there
24 further amendments to the Bill?

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1 Seeing none, the question now occurs on favorably reporting
2 H.R. 5111 as amended to the House. All those in favor shall signify
3 by saying aye.

4 [A chorus of ayes]

5 The Chairman. Those opposed say no. The ayes appear to have
6 it, the ayes have it, and the Bill is favorably reported.

7 The Chair would now call up H.R. 921 as forwarded by the
8 Subcommittee on Health on June 8th, and ask the Clerk to report.

9 [The Bill H.R. 921 follows:]

10

11 *****INSERT 5*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 921, to provide protections for certain
2 sports medicine professionals who provide certain medical
3 services in a secondary state.

4 The Chairman. Without objection the first reading of the Bill
5 is dispensed with, and the Bill will be open for amendment at any
6 point. The Chair would recognize Mr. Guthrie for the purpose of
7 offering an amendment in the nature of a substitute, and the Clerk
8 will report the title.

9 [The Amendment offered by Mr. Guthrie follows:]

10

11 *****INSERT 6*****

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1 The Clerk. Amendment in the nature of a substitute to H.R.
2 921 offered by Mr. Guthrie.

3 The Chairman. The amendment will be considered as read. The
4 Staff will distribute the amendment, and the gentleman is
5 recognized for five minutes.

6 Mr. Guthrie. Thank you, Mr. Speaker. I thank the Ranking
7 Member Green for joining me and offering this amendment from the
8 subcommittee.

9 This bipartisan amendment in the nature of a substitute makes
10 several changes that clarify the scope and intent of the Bill,
11 which currently has 180 bipartisan cosponsors. This legislation
12 addresses a small but important issue. When sports medicine
13 professionals travel with their teams to sporting events out of
14 state, they currently may not be covered by their malpractice
15 insurance in providing care to injured athletes at great personal
16 and professional risk.

17 H.R. 921 will remedy this problem by clarifying that sports
18 medicine professionals will be covered by their professional
19 liability insurance during these limited out-of-state
20 situations.

21 I appreciate the hard work of the committee's staffs on both
22 sides of the aisle they put into polishing this Bill over the last
23 few weeks. Specifically, I want to thank John Stone on the Majority
24 side, and Arielle Woronoff on the Minority staff for all their

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1 work done to get us to where we are today. I also expressly want
2 to thank Megan Jackson on my Staff, who spent countless hours into
3 getting the definitions correct to make sure that we define when
4 a home team is playing and when they're playing out-of-state, so
5 we really appreciate that. I also want to thank legislative
6 counsel for their guidance and expertise in drafting this Bill.

7 I want to encourage my colleagues to vote yes on the amendment
8 and support the final passage of this important Bill, and I yield
9 back the balance of time.

10 The Chairman. The gentleman yields back. The gentleman from
11 Texas, Mr. Green.

12 Mr. Green. Mr. Chairman, I ask strike the last word. I want
13 to thank you, Mr. Chairman and join Mr. Guthrie in offering the
14 amendment in the nature of a substitute. The bipartisan amendment
15 makes improvements on H.R. 921, the Sports Medicine Licensure
16 Clarity Act. The underlying legislation will promote the safety
17 of our athletes by insuring that sports teams, physicians,
18 athletic trainers, and other providers are covered by their
19 malpractice insurance when providing care to injured athletes
20 both home and away, and no matter what across state lines.

21 The change clarifies the scope and intent of the Bill, and
22 I urge my colleagues to support the amendment and final passage
23 of the legislation. And if there are no questions, I'll be glad
24 to yield back.

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1 The Chairman. The gentleman yields back. Further discussion
2 on the amendment? Seeing none, the vote occurs on the amendment
3 in the nature of a substitute. All those in favor will say aye.

4 [A chorus of ayes]

5 The Chairman. Those opposed say no. In the opinion of The
6 Chair, the ayes have it, the ayes have it, and the amendment in
7 the nature of a substitute is agreed to.

8 Further amendment to the Bill? Seeing none, the vote occurs
9 on H.R. 921 as amended. All those in favor will say aye.

10 [A chorus of ayes]

11 The Chairman. Those opposed say no. The opinion of the Chair,
12 the ayes have it, the ayes have it, and the Bill as amended is
13 agreed to.

14 The Chair will now call up H.R. 5104 as forwarded by the
15 Subcommittee on Commerce, Manufacturing and Trade on June 9th,
16 and ask the Clerk to report.

17 [The Bill H.R. 5104 follows:]

18

19 *****INSERT 7*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 5104, to prohibit as an unfair and deceptive
2 act or practice in commerce the sale or use of certain software
3 to circumvent control measures used by internet ticket sellers
4 to insure equitable consumer access to tickets for any given
5 event, and for other purposes.

6 The Chairman. And without objection the first reading of the
7 Bill is dispensed with, and the Bill will be open for amendment
8 at any point. Are there any bipartisan amendments to the Bill?
9 Are there any amendments to the Bill? The gentleman from New
10 Jersey, Mr. Pallone has the amendment at the desk.

11 [The Amendment offered by Mr. Pallone follows:]

12

13 *****INSERT 8*****

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1 Mr. Pallone. Yes, this is the trans -- there are two
2 amendments. This one I guess is D.O.1, Pallone D.O.1.

3 The Chairman. And the Clerk will report the title of the
4 amendment.

5 The Clerk. Amendment to H.R. 5104 offered by Mr. Pallone.

6 The Chairman. And the amendment will be considered as read.
7 The Staff will distribute the amendment, and the gentleman from
8 New Jersey is recognized for five minutes in support of his
9 amendment.

10 Mr. Pallone. Thank you, Mr. Chairman.

11 I support the purpose of H.R. 5014, the BOTS Act, and I
12 support the Bill. At the legislative hearing a few weeks ago,
13 Representative Blackburn said that the purpose of this Bill is
14 to keep the marketplace fair, and my amendment would help insure
15 fairness. While I support this Bill, I don't think it goes far
16 enough. H.R. 5245, the BOSS Act which was introduced by
17 Representative Pascrell and discussed at our last legislative
18 hearing, would take a more comprehensive approach to making ticket
19 buying a positive experience for consumers. So the amendment I
20 am offering incorporates portions of the BOSS Act that will
21 increase transparency and increase fairness for consumers.

22 A few weeks ago, the CEO of Ticketmaster, he was the CEO from
23 2010 to 2013, Nathan Hubbard, wrote that he agreed with the need
24 for increased transparency and fairness. In his article he said

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1 and I quote, "A fan's guide to why you're totally screwed, he
2 called on artists and venues to tell us regular people how many
3 tickets are going on sale." So increased transparency does help
4 consumers. My amendment insures that ticket buyers know how many
5 tickets will be available for sale and how they can get those
6 tickets. It insures consumers understand the true demand for
7 tickets. When only 1,000 tickets of 15,000 are available for the
8 general public, those few tickets will inevitably sell out much
9 faster.

10 The recent CEO of Ticketmaster also called on fans to push
11 venues and promoters to stop charging outrageous ticket fees, and
12 my amendment will at least help ticket buyers know the full price
13 of the ticket, including any additional fees before they decide
14 which tickets to buy so fans can avoid losing out on getting
15 tickets because they wasted time trying to buy tickets they
16 couldn't actually afford due to extra fees that put those tickets
17 out of their budget. And this amendment will prevent scalpers from
18 selling tickets they do not actually have possession of, which
19 insures that consumers are not paying for tickets that they never
20 get.

21 I agree that the use of BOTS in the ticketing marketplace
22 is a problem, but it's just one of many problems. And to truly
23 make the ticketing system work better for consumers, I think we
24 must do more, and this amendment takes another step in that

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1 direction. So I would urge my colleagues to support the amendment,
2 and I yield back.

3 The Chairman. The gentleman yields back. The Chair
4 recognizes the gentlelady from Tennessee, Mrs. Blackburn, for
5 five minutes.

6 Mrs. Blackburn. Thank you, Mr. Chairman.

7 What this amendment would end up doing is to subject live
8 entertainment to a type of regulation that almost no other
9 industry faces. It would require them to place proprietary
10 information in a public domain. We have talked about this; we
11 discussed it as we were in our subcommittee.

12 Now what this would do also, these inventory disclosures that
13 Mr. Pallone would like to see, this would help scalpers to do a
14 better job at what they are trying to do. So it will not make a
15 single additional ticket available to a single additional fan.
16 And I think that we need to realize that this amendment would
17 require disclosure of information that really wouldn't be of any
18 use to the average fan because even if they were aware of it, they
19 wouldn't have a context in which to use the information. What they
20 want to do is be able to click on, choose a seat, and complete
21 that purchase and not have the BOTsters get all the tickets before
22 they have the chance.

23 The other thing we have to do is to look at the artist
24 set-asides and what they do with the tickets for their fan clubs.

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1 And fan clubs are generally open to the public, they're free to
2 join. There is nothing wrong with this. Artists often do deals
3 with credit card companies to give privileged access to a certain
4 credit card holder in return for compensation. It is a business
5 decision that allows them to charge less for the tickets overall.
6 It's a good thing for consumers, and they still remain profitable.

7 And what we want to do is to keep our attention as we focus
8 on making certain that we don't hamper the marketplace. And with
9 that, Mr. Chairman, I will yield my time back.

10 The Chairman. The gentlelady yields back. Other members
11 wishing to -- the gentleman from Pennsylvania, Mr. Doyle.

12 Mr. Doyle. Thank you, Mr. Chairman. Mr. Chairman, I move to
13 strike the last word.

14 First off, I'd like to ask unanimous consent to place two
15 letters from public interest groups supporting comprehensive
16 reforms that are included in the amendment offered by Ranking
17 Member Pallone.

18 The Chairman. Without objection.

19 Mr. Doyle. Thank you. We need to take more substantial steps
20 to bring transparency and accountability to the online ticket
21 sales market. The BOSS Act offered by my friend, Mr. Pascrell,
22 did just that, and I encourage my colleagues to support the
23 amendment offered by our Ranking Member which includes many of
24 the improvements from the BOSS Act.

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1 And, Mr. Chairman, with that, I'll yield back.

2 The Chairman. The gentleman yields back. Other members
3 wishing to speak on the amendment? The gentlelady from Illinois,
4 Ms. Schakowsky, is recognized for five minutes.

5 Ms. Schakowsky. I am speaking in favor of the Ranking
6 Member's amendment. It would include the BOSS Act transparency
7 provisions on the price and availability of tickets creating a
8 better overall environment for ticket buyers. I think both the
9 BOTS and the BOSS Act merit consideration. We should be looking
10 at the online ticket marketplace overall and figuring out how to
11 make it work best for consumers. I think the addition of the BOSS
12 Act which was first introduced by Congressman Pascrell to create
13 more transparency in the ticket market, it was -- it should be
14 added to the legislation that we're doing today to make a really
15 good Bill for consumers. And I yield back.

16 The Chairman. The gentlelady yields back. Other members
17 wishing to speak? Seeing none the vote occurs on the amendment
18 offered by the gentleman from New Jersey, Mr. Pallone. All those
19 in favor will say aye.

20 [A chorus of ayes]

21 The Chairman. Those opposed say no.

22 [A chorus of nos]

23 The Chairman. The nos have it, the nos have it, and the
24 amendment is not agreed to.

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1 Further amendments to the Bill? You want to go? Gentleman
2 from New Jersey has an amendment at the desk.

3 Mr. Pallone. This one is D.O 2.

4 The Chairman. D.O 2 or D.O 1? Is it 2?

5 Mr. Pallone. This is D.O.2.

6 [The Amendment offered by Mr. Pallone follows:]

7

8 *****INSERT 9*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Chairman. The Clerk will report the title of the
2 amendment.

3 The Clerk. Amendment to H.R. 5104 offered by Mr. Pallone.

4 The Chairman. The amendment will be considered as read. The
5 Staff will distribute the amendment, and the gentleman is
6 recognized for five minutes in support of his amendment.

7 Mr. Pallone. Thank you, Mr. Chairman.

8 Again, I support the purpose of the BOTS Act, but this Bill
9 does not do enough to address the problems consumers face in the
10 online ticket marketplace. Since the committee is not taking the
11 additional steps laid out in my previous amendment to help
12 consumers, I'm offering an amendment that would direct the
13 Government Accountability Office to conduct a study of the ticket
14 market to determine the current state of play. In particular, the
15 study would determine who is buying tickets from primary sellers,
16 and how many tickets are resold later, the effect of
17 nontransferable tickets on consumers, and the extent to which BOTS
18 are actually used.

19 While the New York Attorney General report was extremely
20 helpful in identifying many of the problems in the ticketing
21 space, a GAO report could look at the national problems, as well
22 as look at best practices internationally. It also could discuss
23 the pros and cons of potential solutions, such as the suggestion
24 to prevent speculative ticketing selling, and that tickets become

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1 paperless.

2 So my amendment does not change the purpose of the BOTS Act,
3 and it does not make any changes to the current online ticket
4 marketplace. It would only insure that we have some helpful
5 information to help us better consider these issues in the future.
6 And so I hope my colleagues will support my amendment, and I yield
7 back, Mr. Chairman.

8 The Chairman. Are there other members wishing to speak on
9 the amendment? The gentlelady from Tennessee.

10 Mrs. Blackburn. Yes, a couple of things I want to mention
11 about a proposed study. I would want my colleagues to know that
12 you have Senators Schumer, Moran, Blumenthal, and Fischer who are
13 filing a Bill today in the Senate. It doesn't have a study in it.
14 It mirrors the product that we are bringing forward to you today.

15 Now one of the reasons we don't need the GAO to take their
16 time and resources to do a study is because we've already got these
17 from the states. I've got two in my hands, one from New York, and
18 one from Connecticut. The reason we are looking at addressing this
19 on the federal level is because the states have looked at this.
20 And I think that a study would be an unnecessary expense. These
21 studies primarily, they're not performed by the GAO. They're done
22 through the state agencies, and they have been done. We have had
23 those. I think that to turn around and to do this again is just
24 to delay this process.

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1 BOTS are unique an issue because they can't be always handled
2 at a state level. They are interstate in nature. The state studies
3 have shown that. They've already decided that, and that's why we
4 have our Bill. The Senate is putting their companion legislation
5 in today. It is bipartisan. The BOTS Act is a bipartisan Bill,
6 and it seeks to address a narrowly defined interstate problem and
7 regulation of the primary ticketing market, or any of these
8 additional studies is something that we really don't need to spend
9 the time and effort into.

10 With that, Mr. Chairman, I will just yield my time back.

11 The Chairman. The gentlelady yields back. The gentleman from
12 Pennsylvania, Mr. Doyle, is recognized for five minutes.

13 Mr. Doyle. Thank you, Mr. Chairman. I just want to add my
14 voice to support the amendment of the gentleman, and to ask
15 unanimous consent to place a letter from the National Consumers
16 League in the record. Mr. Chairman?

17 The Chairman. If the gentleman might withdraw his amendment,
18 if maybe I can work on a letter asking for a study but not make
19 it part of the Bill, would the gentleman withdraw the amendment?

20 Mr. Doyle. I yield back to Mr. Pallone.

21 The Chairman. I'm sorry. I was in a different --

22 Mr. Doyle. I ask unanimous consent for the National Consumer
23 --

24 The Chairman. Without objection.

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1 Mr. Doyle. Thank you. And I'll yield to Mr. Pallone.

2 Mr. Pallone. Can you just repeat that again?

3 The Chairman. I'm just asking, I do not support adding the
4 amendment to the Bill requesting a study, but I will -- if the
5 gentleman would withdraw the amendment, I will work on a letter
6 requesting a study from GAO, but not as part of the legislation
7 itself.

8 Mr. Pallone. Oh, that's fine.

9 The Chairman. If the gentleman will withdraw his amendment.

10 Mr. Pallone. Sure, I'll withdraw the amendment. Thanks.

11 The Chairman. With that understanding, the gentleman
12 withdraws his amendment. Are there further amendments to the Bill?
13 Seeing none -- I'm sorry, the gentlelady from Illinois has
14 amendment at the desk.

15 [The Amendment offered by Ms. Schakowsky follows:]

16

17 *****INSERT 10*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Chairman. And the Clerk will report the title of the
2 amendment.

3 The Clerk. Amendment to H.R. 5104 offered by Ms. Schakowsky.

4 The Chairman. And without objection the amendment will be
5 considered as read. The Staff will distribute the amendment, and
6 the gentlelady is recognized for five minutes in support of her
7 amendment.

8 Ms. Schakowsky. Thank you, Mr. Chairman.

9 My amendment strengthens the BOTS Act by restoring the civil
10 action provision included when this bill was introduced with
11 bipartisan support last year and again when this bill was
12 reintroduced in April. The civil action provision was not included
13 in the substitute amendment in subcommittee which is unfortunate
14 because it gave the bill real teeth.

15 As Vice Chair Blackburn said in April, "The BOTS Act will
16 allow FTC enforcement and a private right of action to be brought
17 against proven online scalpers. It is time to end this
18 anti-consumer tactics and level the online ticket playing field
19 for fans of live entertainment," she continued.

20 If we want to make real progress in stopping BOTS we need
21 both FTC enforcement and civil action. The FTC has limited
22 resources to enforce this bill all on its own. The original version
23 with both FTC enforcement and civil action had bipartisan support,
24 as I said, from 17 Representatives, including several members of

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1 this committee, as well as the support of the Recording Academy,
2 Pandora, Ticketfly, and LiveNation Entertainment.

3 I urge my colleagues to make this bill stronger and restore
4 the original civil action language. And with that, I yield back.

5 Mr. Pallone. Would the gentlewoman yield?

6 Ms. Schakowsky. Oh, I would yield to the Ranking Member, yes.

7 Mr. Pallone. I just want to support Ms. Schakowsky's
8 amendment. Mrs. Blackburn, as we know, introduced two different
9 versions of this bill. Both versions were bipartisan, and both
10 included a private right of action. And that provision would have
11 allowed consumers who are harmed because someone's use of BOTS
12 to bring a lawsuit against that person in court. So this amendment
13 empowers consumers to protect themselves and seek redress when
14 they're harmed, and this provision has received bipartisan
15 support in the past, and I hope my colleagues will support it now.

16 I yield back.

17 Ms. Schakowsky. And I yield back.

18 The Chairman. The Chair would recognize the gentlelady from
19 Tennessee, Mrs. Blackburn, for five minutes.

20 Mrs. Blackburn. Thank you. And, Mr. Chairman, they are
21 correct. The original BOTS did have a private right of action in
22 it, and that is something that was truly a point of discussion.
23 The reality is, as I have learned through this process, ticketing
24 agents already have access to a private right of action. They have

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1 that private right of action.

2 I will also tell you that the Senate version that Senators
3 Schumer, Moran, Blumenthal, and Fischer are introducing in the
4 Senate does not include a private right of action because they
5 want to actually pass a law that helps consumers, and they know
6 that if a private right of action is included that we're not going
7 to get this signed into law.

8 So we all know that the ticket agents are concerned about
9 the BOT issue. We know that BOTS violate the terms and conditions
10 of the ticketing website, and a BOTster has violated the terms
11 of a contract into which he or she has entered when they utilize
12 the BOT software. So through that, the ticketing agents say they
13 have a private right of action. Ticketmaster has actually
14 successfully sued some scalpers who used BOTS. They've done it
15 several occasions, they have done it under state law. They
16 successfully sued RMG Technologies, a BOT manufacturer in '07,
17 and in Ticketmaster versus Salome and 13 others, they sued
18 operators of a BOT network in 2012. So when we introduced H.R.
19 5104 we recognized that creating a new federal private right of
20 action would bring unnecessary controversy to the bill creating
21 new federal torts which is something that is unnecessary.

22 So with that, yes, the private right of action was moved.
23 The Senate has chosen to keep it out of their bill. We should do
24 likewise. And with that, Mr. Chairman, I yield back.

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1 Ms. Schakowsky. Would the gentlelady yield for just a
2 sentence or two?

3 Mrs. Blackburn. Sure.

4 Ms. Schakowsky. Thank you. You're right that ticket agents
5 would have a state private right of action. Individuals would not,
6 and so this amendment would include individuals in having that.
7 And thank you for yielding.

8 Mrs. Blackburn. Indeed.

9 The Chairman. The gentlelady yields back. Other members
10 wishing to speak on the amendment? Seeing none, the vote occurs
11 on the amendment offered by the gentlelady from Illinois. All
12 those in favor will say aye.

13 [A chorus of ayes]

14 The Chairman. Those opposed say no.

15 [A chorus of nos]

16 The Chairman. Opinion of the Chair, the nos have it.

17 Ms. Schakowsky. I'd like a --

18 The Chairman. Roll call vote is requested. The Clerk will
19 call the roll.

20 The Clerk. Mr. Barton.

21 Mr. Barton. No.

22 The Clerk. Mr. Barton votes no.

23 Mr. Whitfield. Mr. Shimkus.

24 Mr. Shimkus. No.

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1 The Clerk. Mr. Shimkus votes no.

2 Mr. Pitts.

3 Mr. Pitts No.

4 The Clerk. Mr. Pitts votes no.

5 Mr. Walden.

6 Mr. Walden. No.

7 The Clerk. Mr. Walden votes no.

8 Mr. Murphy.

9 Mr. Murphy No.

10 The Clerk. Mr. Murphy votes no.

11 Mr. Burgess.

12 Mr. Burgess. No.

13 The Clerk. Mr. Burgess votes no.

14 Mrs. Blackburn.

15 Mrs. Blackburn. No.

16 The Clerk. Mrs. Blackburn votes no.

17 Mr. Scalise.

18 Mr. Scalise. No.

19 The Clerk. Mr. Scalise votes no.

20 Mr. Latta.

21 Mr. Latta. No.

22 The Clerk. Mr. Latta votes no.

23 Mrs. McMorris Rodgers.

24 Mrs. McMorris Rodgers. No.

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1 The Clerk. Mrs. McMorris Rogers votes no.

2 Mr. Harper.

3 Mr. Harper. No.

4 The Clerk. Mr. Harper votes no.

5 Mr. Lance.

6 Mr. Lance. No.

7 The Clerk. Mr. Lance votes no.

8 Mr. Guthrie.

9 Mr. Guthrie. No.

10 The Clerk. Mr. Guthrie votes no.

11 Mr. Olson.

12 Mr. Olson. No.

13 The Clerk. Mr. Olson votes no.

14 Mr. McKinley.

15 Mr. McKinley. No.

16 The Clerk. Mr. McKinley votes no.

17 Mr. Pompeo.

18 [No response.]

19 The Clerk. Mr. Kinzinger.

20 Mr. Kinzinger. No.

21 The Clerk. Mr. Kinzinger votes no.

22 Mr. Griffith.

23 Mr. Griffith. No.

24 The Clerk. Mr. Griffith votes no.

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1 Mr. Bilirakis.

2 Mr. Bilirakis. No.

3 The Clerk. Mr. Bilirakis votes no.

4 Mr. Johnson.

5 Mr. Johnson. No.

6 The Clerk. Mr. Johnson votes no.

7 Mr. Long.

8 Mr. Long. No.

9 The Clerk. Mr. Long votes no.

10 Mrs. Ellmers.

11 Mrs. Ellmers. No.

12 The Clerk. Mrs. Ellmers votes no.

13 Mr. Bucshon.

14 Mr. Bucshon. No.

15 The Clerk. Mr. Bucshon votes no.

16 Mr. Flores.

17 Mr. Flores. No.

18 The Clerk. Mr. Flores votes no.

19 Mrs. Brooks.

20 Mrs. Brooks. No.

21 The Clerk. Mrs. Brooks votes no.

22 Mr. Mullin.

23 Mr. Mullin. No.

24 The Clerk. Mr. Mullin votes no.

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1 Mr. Hudson.

2 Mr. Hudson. No.

3 The Clerk. Mr. Hudson votes no.

4 Mr. Collins.

5 Mr. Collins. No.

6 The Clerk. Mr. Collins votes no.

7 Mr. Cramer.

8 Mr. Cramer. No.

9 The Clerk. Mr. Cramer votes no.

10 Mr. Pallone.

11 Mr. Pallone. Aye.

12 The Clerk. Mr. Pallone votes aye.

13 Mr. Rush.

14 Mr. Rush. Aye.

15 The Clerk. Mr. Rush votes aye.

16 Ms. Eshoo.

17 Ms. Eshoo. Aye.

18 The Clerk. Ms. Eshoo votes aye.

19 Mr. Engel.

20 [No response.]

21 The Clerk. Mr. Green.

22 Mr. Green. Aye.

23 The Clerk. Mr. Green votes aye.

24 Ms. DeGette.

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1 Ms. DeGette. Aye.

2 The Clerk. Ms. DeGette votes aye.

3 Mrs. Capps.

4 Mrs. Capps. Aye.

5 The Clerk. Mrs. Capps votes aye.

6 Mr. Doyle.

7 Mr. Doyle. Aye.

8 The Clerk. Mr. Doyle votes aye.

9 Ms. Schakowsky.

10 Ms. Schakowsky. Aye.

11 The Clerk. Ms. Schakowsky votes aye.

12 Mr. Butterfield.

13 Mr. Butterfield. Aye.

14 The Clerk. Mr. Butterfield votes aye.

15 Ms. Matsui.

16 Ms. Matsui. Aye.

17 The Clerk. Ms. Matsui votes aye.

18 Ms. Castor.

19 Ms. Castor. Aye.

20 The Clerk. Ms. Castor votes aye.

21 Mr. Sarbanes.

22 Mr. Sarbanes. Aye.

23 The Clerk. Mr. Sarbanes votes aye.

24 Mr. McNerney.

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1 Mr. McNerney. Aye.

2 The Clerk. Mr. McNerney votes aye.

3 Mr. Welch.

4 Mr. Welch. Aye.

5 The Clerk. Mr. Welch votes aye.

6 Mr. Lujan.

7 Mr. Lujan. Aye.

8 The Clerk. Mr. Lujan votes aye.

9 Mr. Tonko.

10 Mr. Tonko. Aye.

11 The Clerk. Mr. Tonko votes aye.

12 Mr. Yarmuth.

13 Mr. Yarmuth. Aye.

14 The Clerk. Mr. Yarmuth votes aye.

15 Ms. Clarke.

16 Ms. Clarke. Aye.

17 The Clerk. Ms. Clarke votes aye.

18 Mr. Loeb sack.

19 Mr. Loeb sack. Aye.

20 The Clerk. Mr. Loeb sack votes aye.

21 Mr. Schrader.

22 Mr. Schrader. Aye.

23 The Clerk. Mr. Schrader votes aye.

24 Mr. Kennedy.

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1 Mr. Kennedy. Aye.

2 The Clerk. Mr. Kennedy votes aye.

3 Mr. Cardenas.

4 Mr. Cardenas. Aye.

5 The Clerk. Mr. Cardenas votes aye.

6 Chairman Upton.

7 Chairman Upton. Votes no.

8 The Clerk. Chairman Upton votes no.

9 The Chairman. Others members wishing to cast a vote or change
10 a vote? Seeing none, the Clerk will report the tally.

11 The Clerk. Mr. Chairman, on that vote there were 22 ayes and
12 29 nos.

13 The Chairman. Twenty-two ayes, 29 nos, the amendment is not
14 agreed to.

15 Are there further amendments to the bill? Seeing none, the
16 question now occurs on favorably reporting H.R. 5104 to the House.
17 All those in favor shall signify by saying aye.

18 [A chorus of ayes]

19 The Chairman. Those opposed say no. Opinion of the Chair,
20 the ayes have it, the ayes have it, and the bill is favorably
21 reported.

22 The Chair would now call up H.R. 670 and ask the Clerk to
23 report.

24 [The Bill H.R. 670 follows:]

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1

2

*****INSERT 11*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 670 to amend Title 29 of the Social Security
2 Act to extend the Medicaid rules regarding supplemental needs
3 trust for Medicaid beneficiaries to trusts established by those
4 beneficiaries and for other purposes.

5 The Chairman. And without objection the first reading of the
6 bill is dispensed with, and the bill will be open for amendment
7 at any point.

8 The Chair would recognize Mr. Lance for the purpose of
9 offering an amendment in the nature of a substitute. And the Clerk
10 will report the title of the amendment.

11 [The Amendment offered by Mr. Lance follows:]

12

13 *****INSERT 12*****

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1 The Clerk. Amendment in the nature of a substitute to H.R.
2 670 offered by Mr. Lance.

3 The Chairman. And the amendment will be considered as read.
4 The Staff will distribute the amendment, and the gentleman from
5 New Jersey is recognized for five minutes in support of his
6 amendment.

7 Mr. Lance. Thank you, Mr. Chairman. I move to strike the last
8 word.

9 Thank you for holding this important markup on this issue.
10 H.R. 670, the Special Needs Trust Fairness Act of 2015 is a
11 targeted improvement to the Medicaid Program. The amendment in
12 the nature of a substitute builds on the underlying bill's
13 commonsense approach. The amendment adds a targeted new benefit
14 for mothers of newborns in requiring State Medicaid Programs to
15 cover tobacco cessation services during the first year of the
16 newborn's life. Under current law, State Medicaid Programs are
17 required to cover cessation services for pregnant women. The
18 policy would extend this to mothers of newborns helping more women
19 make healthy choices, improving their health and the health of
20 their child.

21 This policy was included in the bill that I had sponsored
22 5717, the Medicaid Data and Benefit Improvement Act, and improving
23 access to tobacco cessation services is a policy aim that enjoys
24 wide bipartisan support.

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1 The Centers for Medicare and Medicaid Services has said that
2 cigarette smoking is one of the greatest drivers of adverse health
3 outcomes and costs for state Medicaid programs. By investing in
4 comprehensive tobacco cessation programs, CMS notes that states
5 have reduced smoking rates and health care costs, and have
6 improved health outcomes. In fact, CMS' review of available
7 literature has led the agency to conclude that tobacco treatment
8 is one of the most cost-effective preventative services with as
9 much as a two to three dollar return on every dollar invested.

10 Finally, to offset the increased mandatory outlays from H.R.
11 670, the amendment in the nature of a substitute also includes
12 a policy that would prohibit federal financial participation for
13 drugs used for cosmetic purposes or hair growth except when
14 medically necessary with savings placed in the Medicaid
15 Improvement Fund.

16 I urge my colleagues to adopt this amendment and support the
17 Special Needs Trust Fairness Act. And, Mr. Chairman, I yield back
18 the balance of my time.

19 The Chairman. If the gentleman would just yield for a second.

20 Mr. Lance. Sure.

21 The Chairman. I just want to say that I met with a number
22 of my constituents a couple of weeks ago who were up on the Hill
23 pushing for this legislation, and particularly for families that
24 have a disabled member, I think this is really important. And it

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1 goes along with what we ought to be doing, particularly when the
2 parents or guardians are no longer there. And it's a good
3 bipartisan bill, and I look forward to getting it done on the House
4 floor.

5 Mr. Lance. Thank you, Mr. Chairman.

6 The Chairman. So appreciate the work. Other members wishing
7 to speak on the amendment in the nature of a substitute. Gentleman
8 from New Jersey, Mr. Pallone.

9 Mr. Pallone. Thank you, Mr. Chairman.

10 I strongly support this bipartisan legislation, H.R. 670,
11 the Special Needs Trust Fairness Act. The legislation which I have
12 championed for multiple Congresses now with my Republican
13 colleague, Mr. Glenn Thompson, would allow individuals with
14 disabilities to set up Special Needs Trusts for themselves without
15 a court petition. A Special Needs Trust is a special kind of trust
16 that is designed to provide support for certain expenses for
17 disabled individuals to supplement Medicaid benefits.

18 Currently, these types of trusts generally must be
19 established by parents, grandparents, legal guardians, or a court
20 on behalf of the disabled individual, and those individuals can
21 only set up a Special Needs Trust for themselves after petitioning
22 a court. Oftentimes, this process can take several months and can
23 incur significant legal fees for the disabled individual in the
24 process. And I just don't think that's right; individuals with

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1 disabilities can and should have the ability to set up a Special
2 Needs Trust for themselves, and this legislation fixes that basic
3 inequity.

4 Unfortunately, the legislation before us today is amended
5 by an additional policy that has not been considered through the
6 regular order of the committee, and I want to be clear that I have
7 significant concerns about circumventing our legislative process
8 in this way. Moreover, because H.R. 670 as originally drafted has
9 already passed the Senate, amending this bill further will force
10 reconsideration by the Senate before it can be signed into law.

11 However, with all that, I do -- I don't like the process,
12 obviously, but I believe that H.R. 670 must move forward, and for
13 that reason, I will vote in favor of the bill, and urge my
14 colleagues to vote for it as amended.

15 I yield back.

16 The Chairman. The gentleman yields back. Are there other
17 members wishing to speak on the amendment in the nature of a
18 substitute? Seeing none, the vote occurs on the amendment in the
19 nature of a substitute. All those in favor will signify by saying
20 aye.

21 [A chorus of ayes.]

22 The Chairman. Those opposed say no. The ayes have it, the
23 amendment in the nature of a substitute is agreed to.

24 Are there further amendments to the bill? Seeing none, the

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1 vote occurs on H.R. 670 as amended. All those in favor will say
2 aye.

3 [A chorus of ayes.]

4 The Chairman. Those opposed say no. The opinion of the Chair,
5 the ayes have it, and the bill as amended is agreed to.

6 The Chair will now call up H.R. 5092 and ask the Clerk to
7 report.

8 [The Bill H.R. 5092 follows:]

9

10 *****INSERT 13*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 5092, to make exclusive the authority of the
2 federal government to regulate the labeling of products made in
3 the United States and introduced in interstate or foreign
4 commerce, and for other purposes.

5 The Chairman. And without objection the first reading of the
6 bill is dispensed with, and the bill will be open for amendment
7 at any point. Are there any bipartisan amendments to the bill?
8 Are there any amendments to the bill? The gentleman from
9 Massachusetts might have an amendment at the desk. The Clerk will
10 report the title of the amendment.

11 Mr. Kennedy. It's Ken M.A. 33.

12 [The Amendment offered by Mr. Kennedy follows:]

13

14 *****INSERT 14*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Chairman. Number 33?

2 The Clerk. Amendment to H.R. 5092 offered by Mr. Kennedy.

3 The Chairman. The amendment will be considered as read. The
4 Staff will distribute the amendment, and the gentleman from
5 Massachusetts is recognized for five minutes in support of his
6 amendment.

7 Mr. Kennedy. Thank you, Mr. Chairman.

8 Last month at the Commerce Manufacture and Trade
9 Subcommittee Markup, I offered this same amendment as a compromise
10 to the issues this bill is attempting to address, providing
11 certainty for the business community while insuring that consumer
12 protections remain in place. Last month, I offered and withdrew
13 this amendment under the prospect of the two sides coming together
14 to agree on language that accomplishes both of these goals. I'm
15 pleased to say we had several positive discussions following the
16 subcommittee markup. Unfortunately, I'm disappointed that we were
17 unable to come to an agreement in writing.

18 This legislation seeks to accomplish a worthy goal
19 establishing a singular national standard for what it means to
20 be Made in America. I understand and support that goal. I've heard
21 from manufacturers in my own home state that seek to meet the high
22 standards of manufacturing goods here in the United States, and
23 deservingly should be able to proudly display the Made in America
24 label on their products. However, as currently written the bill

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1 places that goal of business certainty at the expense of
2 consumers. The bill completely preempts any state laws relating
3 to Made in the USA manufacturing claims. This includes any state
4 law providing consumer protection provisions such as state
5 remedies and private rights of action.

6 My amendment balances these interests in three ways. First,
7 it establishes a singular national standard for Made in America
8 labeling requirements for manufactured goods. State would be
9 permitted to pass their own laws so long as the standard is
10 identical to that of the FTC. Second, it would keep state authority
11 and common law consumer protections in place. And third, it
12 provides State Attorneys General the authority to enforce the FTC
13 standard. None of these provisions are groundbreaking, nor are
14 they a dramatic departure from some of the bipartisan policies
15 both sides are supporting today in the other legislation before
16 this committee.

17 As I said last month, it has been my understanding that the
18 sole purpose of this legislation is to create one standard for
19 Made in America manufacturing with which businesses need to
20 comply. This Made in the USA label affixed to products is a
21 valuable tool and a mark of distinction. Businesses meeting the
22 high standard of Made in the USA deserve to proudly display that
23 label on their products, but that mark of distinction cannot come
24 at the expense of consumer protection, and these are not mutually

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1 exclusive goals.

2 I firmly believe that this amendment represents a
3 compromised balance of both the interests of the Majority and the
4 Minority, the business community, and consumer protection
5 advocates. I urge adoption of this amendment, and I yield back
6 the balance of my time.

7 The Chairman. Gentleman yields back his time. Other members
8 wishing to speak? Mr. Harper is recognized for five minutes.

9 Mr. Harper. Thank you, Mr. Chairman. And I certainly
10 appreciate the Congressman's desire to come to an agreement on
11 this, and I was pleased that we've been able to have this
12 discussion.

13 The purpose of this legislation is to establish a single
14 national standard. This is the same text as S. 1518 which passed
15 the Senate Commerce Committee by voice vote, and I'm encouraged
16 that there have been efforts to find compromise prior to this Full
17 Committee Markup. And I do remain hopeful that those conversations
18 can continue after we report out of committee today.

19 Any deal struck at this late date should be the ones that
20 can pass both the House and the Senate. We may be willing to
21 consider some additional state roles, but can only do so in the
22 context of everyone at the table reaching a final agreement that
23 would become law. Absent such an agreement, I cannot support
24 changes to the bill at this time. However, I cannot support a

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1 blanket authorization for 50 Attorneys General to pursue
2 companies trying to comply in good faith with the FTC's
3 guidelines.

4 Companies that manufacture in the United States should be
5 encouraged to label their products as Made in the USA. They
6 shouldn't be sacrificial lambs for the political agendas of state
7 bureaucrats.

8 I believe that a welcome mat for State AGs to penalize the
9 job creators we are trying to help is counter to the intent of
10 this underlying legislation. So this is really, I think, an
11 unnecessary departure from the bill that passed the Senate
12 Commerce Committee by voice vote on a bipartisan basis. I also
13 note that the legislation is a good complement to the FTC Process
14 and Transparency Reform Act which we also voted on today.

15 My bill preempts a set of rules that are currently so
16 difficult to comply with that they might as well be a ban on Made
17 in USA labels. Similarly, the Transparency Reform legislation
18 helps clarify some ambiguity in the kinds of activity that are
19 prohibited under the FTC Act. Together these bills will help U.S.
20 manufacturers keep jobs here, so I certainly would encourage
21 everyone to support the underlying bill, but to vote no on this
22 amendment. And with that, I yield back.

23 The Chairman. The gentleman yields back. The Chair
24 recognizes the gentleman from New Jersey, Mr. Pallone, for five

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1 minutes.

2 Mr. Pallone. Thank you, Mr. Chairman.

3 I'm speaking in support of Mr. Kennedy's amendment. I'm
4 sympathetic to the problem for manufacturers that is caused by
5 multiple standards for using the Made in America label as part
6 of marketing practices, but in my opinion, Mr. Kennedy's amendment
7 strikes the necessary balance. Like the underlying bill, the
8 amendment would ease burdens on manufacturers by creating a single
9 national standard for Made in America advertising, but the
10 amendment would also allow Californians to continue to enforce
11 the national standard as it currently enforces the state standard.
12 It would also allow other State Attorney Generals to enforce the
13 law to protect consumers from true deceptive advertising.

14 I've heard from companies who have tried to comply with the
15 different federal and state standards by creating a different
16 packaging, one type without the Made in America label for sales
17 within a single state, and another type of packing with the label
18 for the rest of the country, but those manufacturers often sell
19 to distributors and retailers, not directly to consumers. In that
20 process, they lose control of where their products go.

21 In at least one situation I heard about the distributor
22 redirected products that were meant for other locations into
23 California, which has a standard for Made in America advertising
24 that is different from the federal standard. California's law

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1 allows enforcement by the California Attorney General, and allows
2 citizens who have been misled by noncompliant advertising to bring
3 cases against the manufacturers. The broad preemption of the
4 underlying bill would stop these avenues of recourse.

5 Under Mr. Kennedy's amendment, consumers who were deceived
6 by noncompliant advertising would still have recourse, but
7 companies acting in good faith won't be subjected to undue
8 burdens. So while I'm generally wary of preemption, it may be
9 merited in this case.

10 So I support this amendment, and I urge my colleagues to
11 support its adoption. I yield back.

12 The Chairman. Gentleman yields back. Other members wishing
13 to speak on the amendment? Seeing -- the gentlelady from Illinois.

14 Ms. Schakowsky. Thank you. I just want to support the Kennedy
15 amendment to allow for state enforcement of the federal standard
16 for the Made in America label. H.R. 5092 preempts state standards
17 for Made in America so there is a single nationwide standard.

18 I understand the desire for a consistent standard among
19 businesses operating in multiple states, but we should not
20 undermine state enforcement if we want the standard to be
21 effective. The FTC has limited resources to insure compliance with
22 its standard. If a state like California wants to enact laws to
23 help enforce the standard, why wouldn't we want to allow that?
24 The Kennedy amendment lets State Attorneys General enforce the

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1 federal standard, and it allows states to adopt the federal
2 standard and enact their own enforcement laws. If we're all for
3 this Made in America label, then I urge adoption of this amendment.
4 I do not believe the bill should advance without it, and I yield
5 back.

6 The Chairman. Gentlelady yields back. Other members wishing
7 to speak on the amendment? Seeing none, the vote occurs on the
8 Kennedy amendment. Those in favor will say aye.

9 [A chorus of ayes.]

10 The Chairman. Those opposed say no.

11 [A chorus of nos.]

12 The Chairman. Opinion of the Chair -- roll call is asked for.
13 The Clerk will call the tally.

14 The Clerk. Mr. Barton.

15 Mr. Barton. No.

16 The Clerk. Mr. Barton votes no.

17 Mr. Whitfield.

18 Mr. Whitfield. No.

19 The Clerk. Mr. Whitfield votes no.

20 Mr. Shimkus.

21 Mr. Shimkus. No.

22 The Clerk. Mr. Shimkus votes no.

23 Mr. Pitts.

24 Mr. Pitts. No.

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1 The Clerk. Mr. Pitts votes no.

2 Mr. Walden.

3 Mr. Walden. No.

4 The Clerk. Mr. Walden votes no.

5 Mr. Murphy.

6 Mr. Murphy. No.

7 The Clerk. Mr. Murphy votes no.

8 Mr. Burgess.

9 Mr. Burgess. No.

10 The Clerk. Mr. Burgess votes no.

11 Mrs. Blackburn.

12 Mrs. Blackburn. No.

13 The Clerk. Mrs. Blackburn votes no.

14 Mr. Scalise.

15 Mr. Scalise. No.

16 The Clerk. Mr. Scalise votes no.

17 Mr. Latta.

18 Mr. Latta. No.

19 The Clerk. Mr. Latta votes no.

20 Mrs. McMorris Rodgers.

21 [No response.]

22 The Clerk. Mr. Harper.

23 Mr. Harper. No.

24 The Clerk. Mr. Harper votes no.

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1 Mr. Lance.

2 Mr. Lance. No.

3 The Clerk. Mr. Lance votes no.

4 Mr. Guthrie.

5 Mr. Guthrie. No.

6 The Clerk. Mr. Guthrie votes no.

7 Mr. Olson.

8 Mr. Olson. No.

9 The Clerk. Mr. Olson votes no.

10 Mr. McKinley.

11 Mr. McKinley. No.

12 The Clerk. Mr. McKinley votes no.

13 Mr. Pompeo.

14 [No response.]

15 The Clerk. Mr. Kinzinger.

16 Mr. Kinzinger. No.

17 The Clerk. Mr. Kinzinger votes no.

18 Mr. Griffith.

19 Mr. Griffith. No.

20 The Clerk. Mr. Griffith votes no.

21 Mr. Bilirakis.

22 Mr. Bilirakis. No.

23 The Clerk. Mr. Bilirakis votes no.

24 Mr. Johnson.

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1 [No response.]

2 The Clerk. Mr. Long.

3 Mr. Long. No.

4 The Clerk. Mr. Long votes no.

5 Mrs. Ellmers.

6 Mrs. Ellmers. No.

7 The Clerk. Mrs. Ellmers votes no.

8 Mr. Bucshon.

9 Mr. Bucshon. No.

10 The Clerk. Mr. Bucshon votes no.

11 Mr. Flores.

12 Mr. Flores. No.

13 The Clerk. Mr. Flores votes no.

14 Mrs. Brooks.

15 Mrs. Brooks. No.

16 The Clerk. Mrs. Brooks votes no.

17 Mr. Mullin.

18 Mr. Mullin. No.

19 The Clerk. Mr. Mullin votes no.

20 Mr. Hudson.

21 Mr. Hudson. No.

22 The Clerk. Mr. Hudson votes no.

23 Mr. Collins.

24 Mr. Collins. No.

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1 The Clerk. Mr. Collins votes no.

2 Mr. Cramer.

3 Mr. Cramer. No.

4 The Clerk. Mr. Cramer votes no.

5 Mr. Pallone.

6 Mr. Pallone. Aye.

7 The Clerk. Mr. Pallone votes aye.

8 Mr. Rush.

9 Mr. Rush. Aye.

10 The Clerk. Mr. Rush votes aye.

11 Ms. Eshoo.

12 Ms. Eshoo. Aye.

13 The Clerk. Ms. Eshoo votes aye.

14 Mr. Engel.

15 [No response.]

16 The Clerk. Mr. Green.

17 Mr. Green. Aye.

18 The Clerk. Mr. Green votes aye.

19 Ms. DeGette.

20 Ms. DeGette. Aye.

21 The Clerk. Ms. DeGette votes aye.

22 Mrs. Capps.

23 Mrs. Capps. Aye.

24 The Clerk. Mrs. Capps votes aye.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Doyle.

2 Mr. Doyle. Aye.

3 The Clerk. Mr. Doyle votes aye.

4 Ms. Schakowsky.

5 Ms. Schakowsky. Aye.

6 The Clerk. Ms. Schakowsky votes aye.

7 Mr. Butterfield.

8 Mr. Butterfield. Aye.

9 The Clerk. Mr. Butterfield votes aye.

10 Ms. Matsui.

11 Ms. Matsui. Aye.

12 The Clerk. Ms. Matsui votes aye.

13 Ms. Castor.

14 Ms. Castor. Aye.

15 The Clerk. Ms. Castor votes aye.

16 Mr. Sarbanes.

17 Mr. Sarbanes. Aye.

18 The Clerk. Mr. Sarbanes votes aye.

19 Mr. McNerney.

20 Mr. McNerney. Aye.

21 The Clerk. Mr. McNerney votes aye.

22 Mr. Welch.

23 Mr. Welch. Aye.

24 The Clerk. Mr. Welch votes aye.

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1 Mr. Lujan.

2 Mr. Lujan. Aye.

3 The Clerk. Mr. Lujan votes aye.

4 Mr. Tonko.

5 Mr. Tonko. Aye.

6 The Clerk. Mr. Tonko votes aye.

7 Mr. Yarmuth.

8 Mr. Yarmuth. Aye.

9 The Clerk. Mr. Yarmuth votes aye.

10 Ms. Clarke.

11 Ms. Clarke. Aye.

12 The Clerk. Ms. Clarke votes aye.

13 Mr. Loeb sack.

14 Mr. Loeb sack. Aye.

15 The Clerk. Mr. Loeb sack votes aye.

16 Mr. Schrader.

17 Mr. Schrader. Aye.

18 The Clerk. Mr. Schrader votes aye.

19 Mr. Kennedy.

20 Mr. Kennedy. Aye.

21 The Clerk. Mr. Kennedy votes aye.

22 Mr. Cardenas.

23 Mr. Cardenas. Aye.

24 The Clerk. Mr. Cardenas votes aye.

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1 Chairman Upton.

2 Chairman Upton. Votes no.

3 The Clerk. Chairman Upton votes no.

4 The Chairman. Other members wishing to cast a vote or change
5 a vote? Mr. Johnson.

6 Mr. Johnson. No.

7 The Clerk. Mr. Johnson votes no.

8 The Chairman. Other members? Seeing none, the Clerk will
9 report the tally.

10 The Clerk. Mr. Chairman, on that vote there were 22 ayes and
11 29 nos.

12 The Chairman. Twenty-two ayes, 29 nos, the amendment is not
13 agreed to.

14 Are there further amendments to the bill? Seeing none, the
15 vote occurs on H.R. 5092. Those in favor will say aye.

16 [A chorus of ayes]

17 The Chairman. Those opposed say no.

18 [A chorus of nos]

19 The Chairman. Opinion of the Chair, the ayes have it. A roll
20 call was asked for. So a roll call is asked for. I would note that
21 when this roll call is done, vote has been called on the House.
22 We will recess until 8:00 p.m. Okay, 8 p.m., and the Clerk will
23 call the roll.

24 The Clerk. Mr. Barton.

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1 Mr. Barton. Yes.

2 The Clerk. Mr. Barton votes aye.

3 Mr. Whitfield.

4 Mr. Whitfield. Aye.

5 The Clerk. Mr. Whitfield votes aye.

6 Mr. Shimkus.

7 Mr. Shimkus. Aye.

8 The Clerk. Mr. Shimkus votes aye.

9 Mr. Pitts.

10 Mr. Pitts. Aye.

11 The Clerk. Mr. Pitts votes aye.

12 Mr. Walden.

13 Mr. Walden. Aye.

14 The Clerk. Mr. Walden votes aye.

15 Mr. Murphy.

16 Mr. Murphy. Aye.

17 The Clerk. Mr. Murphy votes aye.

18 Mr. Burgess.

19 Mr. Burgess. Aye.

20 The Clerk. Mr. Burgess votes aye.

21 Mrs. Blackburn.

22 Mrs. Blackburn. Aye.

23 The Clerk. Mrs. Blackburn votes aye.

24 Mr. Scalise.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 [No response.]

2 The Clerk. Mr. Latta.

3 Mr. Latta. Aye.

4 The Clerk. Mr. Latta votes aye.

5 Mrs. McMorris Rodgers.

6 [No response.]

7 The Clerk. Mr. Harper.

8 Mr. Harper. Aye.

9 The Clerk. Mr. Harper votes aye.

10 Mr. Lance.

11 Mr. Lance. Aye.

12 The Clerk. Mr. Lance votes aye.

13 Mr. Guthrie.

14 Mr. Guthrie. Aye.

15 The Clerk. Mr. Guthrie votes aye.

16 Mr. Olson.

17 Mr. Olson. Aye.

18 The Clerk. Mr. Olson votes aye.

19 Mr. McKinley.

20 Mr. McKinley. Aye.

21 The Clerk. Mr. McKinley votes aye.

22 Mr. Pompeo.

23 [No response.]

24 The Clerk. Mr. Kinzinger.

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1 Mr. Kinzinger. Aye.

2 The Clerk. Mr. Kinzinger votes aye.

3 Mr. Griffith.

4 Mr. Griffith. Aye.

5 The Clerk. Mr. Griffith votes aye.

6 Mr. Bilirakis.

7 Mr. Bilirakis. Aye.

8 The Clerk. Mr. Bilirakis votes aye.

9 Mr. Johnson.

10 Mr. Johnson. Aye.

11 The Clerk. Mr. Johnson votes aye.

12 Mr. Long.

13 Mr. Long. Aye.

14 The Clerk. Mr. Long votes aye.

15 Mrs. Ellmers.

16 Mrs. Ellmers. Aye.

17 The Clerk. Mrs. Ellmers votes aye.

18 Mr. Bucshon.

19 Mr. Bucshon. Aye.

20 The Clerk. Mr. Bucshon votes aye.

21 Mr. Flores.

22 Mr. Flores. Aye.

23 The Clerk. Mr. Flores votes aye.

24 Mrs. Brooks.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mrs. Brooks. Aye.

2 The Clerk. Mrs. Brooks votes aye.

3 Mr. Mullin.

4 Mr. Mullin. Aye.

5 The Clerk. Mr. Mullin votes aye.

6 Mr. Hudson.

7 Mr. Hudson. Aye.

8 The Clerk. Mr. Hudson votes aye.

9 Mr. Collins.

10 Mr. Collins. Aye.

11 The Clerk. Mr. Collins votes aye.

12 Mr. Cramer.

13 Mr. Cramer. Aye.

14 The Clerk. Mr. Cramer votes aye.

15 Mr. Pallone.

16 Mr. Pallone. I'm sorry. No.

17 The Clerk. Mr. Pallone votes no.

18 Mr. Rush.

19 Mr. Rush. No.

20 The Clerk. Mr. Rush votes no.

21 Ms. Eshoo.

22 Ms. Eshoo. No.

23 The Clerk. Ms. Eshoo votes no.

24 Mr. Engel.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 [No response.]

2 The Clerk. Mr. Green.

3 Mr. Green. No.

4 The Clerk. Mr. Green votes no.

5 Ms. DeGette.

6 Ms. DeGette. No.

7 The Clerk. Ms. DeGette votes no.

8 Mrs. Capps.

9 Mrs. Capps. No.

10 The Clerk. Mrs. Capps votes no.

11 Mr. Doyle.

12 Mr. Doyle. No.

13 The Clerk. Mr. Doyle votes no.

14 Ms. Schakowsky.

15 Ms. Schakowsky. No.

16 The Clerk. Ms. Schakowsky votes no.

17 Mr. Butterfield.

18 Mr. Butterfield. No.

19 The Clerk. Mr. Butterfield votes no.

20 Ms. Matsui.

21 Ms. Matsui. No.

22 The Clerk. Ms. Matsui votes no.

23 Ms. Castor.

24 Ms. Castor. No.

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1 The Clerk. Ms. Castor votes no.

2 Mr. Sarbanes.

3 Mr. Sarbanes. No.

4 The Clerk. Mr. Sarbanes votes no.

5 Mr. McNerney.

6 Mr. McNerney. No.

7 The Clerk. Mr. McNerney votes no.

8 Mr. Welch.

9 Mr. Welch. No.

10 The Clerk. Mr. Welch votes no.

11 Mr. Lujan.

12 Mr. Lujan. No.

13 The Clerk. Mr. Lujan votes no.

14 Mr. Tonko.

15 Mr. Tonko. No.

16 The Clerk. Mr. Tonko votes no.

17 Mr. Yarmuth.

18 Mr. Yarmuth. No.

19 The Clerk. Mr. Yarmuth votes no.

20 Ms. Clarke.

21 Ms. Clarke. No.

22 The Clerk. Ms. Clarke votes no.

23 Mr. Loeb sack.

24 Mr. Loeb sack. No.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. Mr. Loeb sack votes no.

2 Mr. Schrader.

3 Mr. Schrader. Aye.

4 The Clerk. Mr. Schrader votes aye.

5 Mr. Kennedy.

6 Mr. Kennedy. No.

7 The Clerk. Mr. Kennedy votes no.

8 Mr. Cardenas.

9 Mr. Cardenas. No.

10 The Clerk. Mr. Cardenas votes no.

11 Chairman Upton.

12 Chairman Upton. Votes aye.

13 The Clerk. Chairman Upton votes aye.

14 The Chairman. Other members wishing to cast a vote or change
15 their vote? Seeing none, the Clerk will report the tally. Reminder
16 as the Clerk does the tally that we are coming back at 8:00. We're
17 recessing until 8:00 to finish the last two bills.

18 The Clerk. Mr. Chairman, on that vote there were 29 ayes,
19 21 nos.

20 The Chairman. Twenty-nine ayes, 21 nos, the bill is agreed
21 to and favorably reported.

22 The committee stands in recess.

23 [Recess.]

24 The Chairman. All right, back in session here.

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1 The Chair will call up H.R. 3299 as forwarded by the
2 Subcommittee on Health on June 8th, and ask the Clerk to report.

3 [The Bill H.R. 3299 follows:]

4

5 *****INSERT 15*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. H.R. 3299, to amend the Public Health Service Act
2 to insure preparedness for chemical, radiological, biological,
3 and nuclear threats, and for other purposes.

4 The Chairman. And without objection the first reading of the
5 bill is dispensed with, and the bill will be open for amendment
6 at any point. And I understand Mrs. Brooks has an amendment in
7 the nature of a substitute. And the Clerk will report the title.

8 [The Amendment offered by Mrs. Brooks follows:]

9

10 *****INSERT 16*****

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 The Clerk. Amendment in the nature of a substitute to H.R.
2 3299 offered by Mrs. Brooks.

3 The Chairman. And without objection the amendment is
4 considered as read. The Staff will distribute the amendment, and
5 the gentlelady is recognized for five minutes in support of her
6 amendment.

7 Mrs. Brooks. Thank you, Mr. Chairman.

8 Out the outset, I want to begin by thanking my partner in
9 crafting this bill, Congresswoman Eshoo, who has truly been an
10 expert in this field. Our ability to craft this comprehensive bill
11 together proves that partisanship truly has no place when it comes
12 to protecting our homeland.

13 As an original author of Project Bioshield, Congresswoman
14 Eshoo crafted Project Bioshield. She knows how multilayered and
15 complicated our preparedness enterprise is. H.R. 3299 has
16 significant and real reforms to continue to strengthen and
17 expedite how we as a country are prepared to respond to biological
18 threats.

19 This amendment in the nature of a substitute does the
20 following: Requires BARDA and the CDC to coordinate medical
21 countermeasures for what's called the Strategic National
22 Stockpile. It removes outdated and bureaucratic steps in the
23 procurement contract process to expedite critical medical
24 countermeasures procurement contracts, and it returns

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1 contracting authority to the BARDA Director as is currently in
2 statute, although not currently in practice. It creates a Priority
3 Review Voucher Program for all material threats identified by the
4 Department of Homeland Security as direct threats to our national
5 security. And if you don't know what those material threats are,
6 they are things like anthrax, smallpox, cyanide threats, threats
7 that will kill volumes and volumes of people if infected
8 throughout our country.

9 And, finally, as the front line of any outbreak or biologic
10 weapon attack, our hospitals and first responders must be equipped
11 with the resources they need as we saw during the ebola outbreak
12 to safely and effectively respond.

13 Our bill requires the GAO to conduct a review of the Hospital
14 Preparedness Program and the Public Health Emergency Preparedness
15 Grants to insure that the goals are being met and to identify
16 potential readiness gaps.

17 There's a reason that six of the items -- there are six of
18 the items on the Material Threat List that has 13 items that have
19 no developed vaccine or treatment or whatsoever. That's because
20 medical countermeasures are incredibly challenging and unique.
21 On average, it takes 14 years to develop a medical countermeasure
22 with no guarantee of their success by the companies that undertake
23 them. Given the length of time it takes to develop a countermeasure
24 and the shear complexity and uncertainty of the process it's

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1 imperative that we keep our private sector partners engaged. The
2 PRV Programs have proven effective, zero cost to the taxpayer,
3 commonsense way of achieving this goal, and incentivizing
4 countermeasure development to protect the American people.

5 We have the support of the following groups: The American
6 Hospital Association, Trust for America's Health, the Department
7 of Army, the Alliance for Biosecurity, VC Investors in Biotech,
8 and the Blue Ribbon Study Panel on Biodefense. I'd like to ask
9 unanimous consent to submit their letters of support for the
10 record.

11 The Chairman. Without objection.

12 Mrs. Brooks. And with that, I'd like to yield the remainder
13 of my time to my partner on this bill, and a strong leader in
14 biodefense space, Congresswoman Eshoo.

15 Ms. Eshoo. I thank the gentlewoman both for your good words,
16 your outstanding work, and for being a terrific partner in this,
17 and I couldn't mean it more.

18 My colleagues, I know this bill very well because I wrote
19 it, and I wrote it with Mike Rogers in 2006, and it was signed
20 into law at the time. And it was on the heels, obviously, of the
21 post-9/11 era, and what we were being advised here in terms of
22 preparedness relative to bioterrorism.

23 Now, Mrs. Brooks has outlined the list of changes. Many of
24 them are small, but there are two that stand out that I think I

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1 want to emphasize because I think they are two areas that members
2 are not so familiar with. The one in terms of contracting is really
3 not a change. It was in the original legislation, and then it
4 changed within the bureaucracy. I believe -- we believe that this
5 belongs within BARDA because we have to have timeliness in terms
6 of approval. You can't have one product take 17 months to be
7 approved. We will not have a stockpile of what we need.

8 What is new in the bill, which I think is a very important
9 change, is the Priority Review Voucher. Understand there's no
10 public money in this, they are private dollars. Homeland Security
11 comes up with the list. If a company chooses to use the Priority
12 Review Voucher, the FDA must approve it.

13 So I think these are sound recommendations. I think they are
14 important for our national security. I think the stockpile of what
15 needs to be created in terms of a biodefense for our country is
16 absolutely essential, and I think that BARDA will be strengthened
17 in order to do the job that needs to be done in order to protect
18 our country.

19 So I don't think I have any of your time left, Congresswoman
20 Brooks, but I thank you for yielding time to me, and again for
21 your partnership and wonderful work.

22 The Chairman. The gentlelady's time has expired. Other
23 members wishing to speak on the amendment in the nature of a
24 substitute? Seeing none, the vote occurs on that amendment. All

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1 those in favor will say aye.

2 [A chorus of ayes.]

3 The Chairman. Those opposed, nay. In the opinion of the
4 Chair, the ayes have it, the ayes have it, and the amendment in
5 the nature of a substitute is agreed to.

6 Are there other amendments to the bill? Gentleman from New
7 Jersey has an amendment at the desk. The Clerk will call the title

8 -- -

9 [The Amendment offered by Mr. Pallone follows:]

10

11 *****INSERT 17*****

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1 Mr. Pallone. The first one is number 2.

2 The Chairman. The Clerk will read the title.

3 The Clerk. Amendment to the amendment in the nature of a
4 substitute -- -

5 The Chairman. Oh, wait, wait.

6 Mr. Pallone. Oh, I'm sorry, it's 01. I apologize; 01 relating
7 to the contract authority.

8 The Clerk. Amendment to the amendment in the nature of a
9 substitute to H.R. 3299 offered by Mr. Pallone.

10 The Chairman. And the amendment will be considered as read.
11 The Staff will distribute the amendment, and the gentleman from
12 New Jersey is recognized for five minutes in support of his
13 amendment.

14 Mr. Pallone. Thank you, Mr. Chairman.

15 As was mentioned by the sponsors, the bill delegates
16 contracting authority directly to the BARDA Director, and the
17 purpose of this amendment is to keep the current structure; in
18 other words, where the Assistant Secretary for Public Response
19 or ASPR, has to approve it. What we're trying to do with this
20 amendment is not eliminate the level of approval by the Assistant
21 Secretary, because I think it protects the integrity of the
22 contracting process.

23 So, Mr. Chairman, since the reorganization of the Office of
24 the Assistant Secretary of Preparedness and Response at ASPR,

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1 which consolidated organizational wide contracting activities,
2 BARDA has experienced an acceleration in the delivery of medical
3 countermeasures. For example, the total 23 products that BARDA
4 has supported that received FDA approval licensure or clearance,
5 14 of those approvals have occurred since 2011, and five have
6 occurred in the last 16 months. And BARDA is also currently
7 supporting a pipeline of over 100 more.

8 In addition to the success with delivering medical
9 countermeasures, the AMC's execution of BARDA contracting
10 activity has exceeded governmental benchmarks. The
11 Department-wide benchmark for contract issuance is 180 days, the
12 average for BARDA contracts is 129 days. The last seven major
13 acquisitions have actually occurred even faster reaching
14 completion in 90 days with only two of those contracts exceeding
15 100 days.

16 Additionally, the contracting office has proven that it can
17 deliver in times of emergency. For example, in response to the
18 FDA guidance that it was going to require blood collection in areas
19 with active Zika transmission to be sought, the contracting office
20 issued contracts to support the emergency delivery of blood to
21 Puerto Rico within six business days. So based on this, I agree
22 with Dr. Hatchett, the Acting Director of BARDA who stated at our
23 hearing on this legislation that "after looking at the data it
24 does not support the restructuring required by this bill. The data

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1 makes clear the contracting office is exceeding performance
2 expectations and helping BARDA fulfill its mission to advance
3 national security by helping to protect against terrorism and
4 other public health threats. In addition to concluding the move
5 is unnecessary, I also have concerns with problems that would
6 arise from the proposed change. I have concerns about the
7 delegation of the function to negotiate and enter into contracts,
8 grants, and cooperative agreements to the BARDA Director.
9 Currently, BARDA enters into contracts through the office that
10 asks for its parent organization, and this structure protects the
11 integrity of the contracting process."

12 After Secretary Sebelius provided Congress with notice and
13 published the required announcement in the Federal Register in
14 2010, contracting offices were removed from BARDA and other
15 divisional entities within ASPR and consolidated. The
16 restructuring of the contract offices was done to streamline
17 ASPR's contracting activity to bolster program integrity, and to
18 insure that ASPR and all of its operating divisions conduct their
19 business without either the perception or potentially the reality
20 of undue influence by program officials. And that restructuring
21 allowed the office or the head of contracting activity to be
22 successful. It basically removed the need for the contracting
23 office to go through an additional layer of approval.

24 So my point is that the current structure which is consistent

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1 with procurement practices across the federal government insures
2 the right balance between expert scientists that advance our
3 national preparedness and expert contracting professionals that
4 insure the government is getting the best value for every taxpayer
5 dollar. And I think this integrity minded structure established
6 by ASPR has not only contributed to a steadily improved
7 contracting process, but also one that has successfully withstood
8 the few protests presented to the organization.

9 I don't want to continue with this, Mr. Chairman, but my point
10 is, I don't really see the need for the restructuring to have to
11 eliminate the overview, if you will, of ASPR and just have the
12 contract -- the BARDA Director do the contracting directly. I'll
13 yield back the balance of my time.

14 The Chairman. Gentleman yields back. The Chair recognizes
15 Mr. Flores.

16 Mr. Flores. And I can defer to Ms. Eshoo, if you'd like her
17 to go first. She was holding her hand up first. You want me to
18 go?

19 The Chairman. Please.

20 Mr. Flores. Okay. Thank you, Mr. Chairman.

21 I applaud the great work of Congresswoman Eshoo, and also
22 Congresswoman Brooks on this bill. The Strengthening Public
23 Health Emergency Response Act is about protecting our
24 constituents from public health emergencies and biochemical

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1 attacks. This bill seeks to create an environment where the
2 private sector and the federal government can work
3 collaboratively in the most efficient manner to create medical
4 countermeasures, known as MCM, to protect the American people.

5 An important component of this bill is that it repairs the
6 damage done to this goal by the HHS attempts to arbitrarily modify
7 the BARDA contracting progress. And so contrary to the goal of
8 this bill, the Pallone Amendment seeks to limit BARDA's
9 contracting authority. This amendment jeopardizes U.S. national
10 security by undermining efficiency and, ultimately, slowing down
11 MCM development at BARDA as it may continue to face roadblocks
12 and be slow an inefficient.

13 When government is an impediment, it discourages many
14 private sector partners and public sectors partners out of this
15 critical work leaving the American people vulnerable to epidemics
16 and biowarfare attacks.

17 When BARDA was created in 2006, Congress and this committee
18 gave the agency the sole authority to negotiate and execute its
19 biomedical countermeasure advance development contracts. And
20 Congress on a bipartisan basis viewed this contracting authority
21 as a critical component of BARDA's unique national security
22 mission. And it was intended to function similar to the Department
23 of Defense with nimble and flexible contracting procedures.
24 Despite the intent of Congress, BARDA's contracting authority was

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1 removed by HHS in 2009, and authority over all of BARDA's contracts
2 was moved to the Office of Acquisitions Management Contracts and
3 Grants, ACMG, within the Office of the Assistant Secretary for
4 Preparedness and Response, ASPR. This cumbersome arrangement has
5 created confusion, unnecessary delays, and uncertainty regarding
6 time-sensitive medical countermeasure contracts, and is counter
7 to BARDA's mission to be flexible, nimble, and efficient.

8 ACMG's review and approval process is often slow,
9 burdensome, and inefficient. For example, at BARDA's insistence
10 insurance companies -- excuse me -- companies often respond to
11 urgent requests to submit proposals within a 24 to 48-hour
12 turnaround only to have these proposals languish in ACMG's review
13 process for multiple weeks or even months. ACMG does not appear
14 to have an understanding or an appreciation of the complexities
15 of vaccine or MCM development and how lengthy, and flexible, and
16 burdensome review can delay timelines, or worse cause entities
17 to question their partnership with HHS.

18 For example, Texas A&M University is my congressional
19 district, and operates one of three vaccine research and
20 development centers for BARDA. This institution has experienced
21 significant frustrations and delays in dealing with the
22 contracting schematic that was disconnected from the BARDA
23 mission. The contracting team did not appear to understand many
24 of the basic tenets of cost reimbursement contracts leaving the

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1 State of Texas and Texas A&M as an institution having to cover
2 capital outlays beyond any reasonable period that the private
3 sector would consider acceptable.

4 Furthermore, the contracting team was not in step with the
5 scope and mission, the request from BARDA's Director's office.
6 In a time of national emergency, the public cannot afford delays
7 or misalignment of the process with the mission. The contracting
8 authority needs to be aligned now, not as an afterthought
9 following a national emergency. There is broad agreement among
10 Congress and independent experts that BARDA should be allowed to
11 negotiate, manage, and award its own contracts as it has done
12 effectively and efficiently in the past. BARDA's former Director
13 who served for the last 10 years even testified to this committee
14 that restoring BARDA's contracting authority would improve MCM
15 development.

16 In 2015, the Blue Ribbon Study Panel on Defense recommended
17 that the contracting authority be returned to BARDA citing the
18 importance of BARDA's national security mission within HHS. So
19 returning contracting authority back to BARDA would not cost the
20 taxpayers a dime, it would not put any burdens on HHS, and it would
21 not jeopardize the integrity of the contracting process. It would,
22 however, be consistent with how Congress envisioned BARDA to
23 function.

24 I urge my colleagues to oppose the Pallone Amendment and to

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1 allow contracting authority for BARDA, and I appreciate
2 Congresswoman Eshoo and Congresswoman Brooks for fixing this
3 critical issue with respect to the way HHS operates today. Thank
4 you, and I yield back the balance of my time.

5 The Chairman. The gentleman yields back. Other members
6 wishing to speak? The gentlelady from California, Ms. Eshoo.

7 Ms. Eshoo. Thank you, Mr. Chairman. I move to strike the last
8 word.

9 My colleagues, this is a very important part of the bill,
10 and I know at 8:30 at night the last thing you probably feel like
11 even listening to are the innards of contracts at a small agency
12 that most of you are not familiar with. But this is -- this really
13 goes to the heart of how this very small but supposed to be limber
14 agency is to work, because if the contracting is stretched out,
15 not effective, not efficient, then you're not going to get
16 product. And that's what we're after, that's why we set this
17 operation up.

18 Now, as Congressman Flores, and I appreciate your good words,
19 pointed out there was Blue Ribbon Study Panel on Biodefense.
20 Former Senator Joe Lieberman was -- and he was the former Chairman
21 of the Senate Homeland Security Committee, and the former
22 Secretary of Homeland Security, Tom Ridge, published an 82-page
23 report on the subject, and it included a recommendation that BARDA
24 contracting authorities be reinstated.

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1 Now what happened from the time the ink dried when it became
2 law that stipulated that BARDA would do the contracting, and now
3 our Ranking Member is offering an amendment to keep it to where
4 it has drifted to. And it has drifted, it has not worked out well.

5 I want to offer a quote from a 2011 story in the New York
6 Times Magazine which highlighted the inefficiencies of the
7 contracting situation. And it was stated that the person that was
8 -- it had drifted to "had removed from BARDA all the contracting
9 officers instructing them to report to her instead of Robinson."
10 I don't know how these people took away what was originally what
11 was in the law, but if it were working well, you know what, I'd
12 let it fly. I wouldn't be talking to you at 8:30 at night about
13 this. But it was said by those that worked with them, "We actually
14 spend as much time managing our contracts as we do trying to
15 develop our drugs." And that's not why we did the legislation,
16 it's not why it became law.

17 Now Dr. Robinson, who headed up BARDA for 10 years said, "If
18 there was anything to be done, it was to keep the contracting in
19 BARDA." I think that, obviously, all the -- everything that is
20 a part of not only transparency but what needs to be kept and put
21 into place relative to conflict of interest, all of that have to
22 guide contracting. But if it is not working and operating
23 efficiently, I think that Congress needs to say something and step
24 in on this. Otherwise, most frankly, I wouldn't bother with it.

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1 If I thought this was a pesky fly, I wouldn't -- in terms of an
2 issue, I wouldn't place this much of an emphasis on it. But it
3 is very important.

4 And how did we model the original legislation that became
5 law? We modeled it after DARPA. We modeled it after DARPA. DARPA
6 does its own contracting, and DARPA is hailed by all of us on both
7 sides of the aisle. So we worked hard, and I think that we produced
8 a product at that time that really made sense and has worked.

9 So it isn't too often I disagree with the Ranking Member,
10 but I do on this one. The other agency that seems to have taken
11 over this contracting issue or operation is very unhappy. And I
12 met with the doctor who heads it up, and it was not an easy meeting;
13 many questions left unanswered. And she promised that she would
14 get recommendations to me to improve the legislation, and we've
15 never received such.

16 So given all of this backdrop, I really recommend that this
17 suggestion by way of an amendment not be accepted for all the
18 reasons that I stated. It's modeled after DARPA, the original
19 Director said this is the heart of the program in terms of
20 efficiency and timeliness, which is essential for bioterrorism
21 products. And there was a commission or a Blue Ribbon Committee
22 that included that recommendation for contracting authorities
23 being reinstated. I think that's one heck of a record on this item,
24 and I thank -- I yield back the non-balance of my time.

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1 The Chairman. The gentlelady's time is expired. Other
2 members wishing to speak on the amendment? Seeing none, the vote
3 occurs on the amendment offered by the gentleman from New Jersey.
4 All those in favor say aye.

5 [A chorus of ayes.]

6 The Chairman. Those opposed say no.

7 [A chorus of nos.]

8 The Chairman. Opinion of the Chair, the nos have it, the nos
9 have it, the amendment is not agreed to.

10 Are there other amendments to the amendment -- the gentleman
11 from New Jersey has another amendment?

12 Mr. Pallone. Yes, this one is number 2.

13 The Chairman. Number 2, and the Clerk will report the title
14 of the amendment.

15 [The Amendment offered by Mr. Pallone follows:]

16

17 *****INSERT 18*****

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1 The Clerk. Amendment to the amendment in the nature of a
2 substitute to H.R. 3299 offered by Mr. Pallone.

3 The Chairman. And the amendment will be considered as read.
4 The Staff will distribute the amendment, and the gentleman is
5 recognized for five minutes in support of his amendment.

6 Mr. Pallone. Thank you, Mr. Chairman.

7 The substitute that we voted on today to H.R. 3299 would
8 create a new permanent Priority Review Voucher, or PRV program
9 for medical countermeasures. And for this reason, I can't support
10 the bill as amended by the substitute.

11 I have on several occasions voiced concerns with extending
12 PRV programs to include medical countermeasures as I believe it's
13 an unnecessary incentive in this space. A 2014 Congressional
14 Research Service report found that since 2004, the federal
15 government has spent over \$3 billion procuring medical
16 countermeasures, and this is in addition to the hundreds of
17 millions of dollars HHS and DoD awarded drug companies each year
18 to support medical countermeasure research and development.

19 For example, HHS reported it would spend over \$830 million
20 during the 2015 fiscal year to support medical countermeasure
21 research, development, and procurement through BARDA and Project
22 Bioshield. Providing an additional PRV incentive, the last of
23 which sold for \$350 million to drug companies already receiving
24 significant taxpayer support seems inappropriate and

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1 unnecessary. However, if this legislation is enacted, I believe
2 it is important to insure it is actually incentivizing new
3 research and development of medical countermeasures. And as such,
4 I'm offering an amendment to sunset the program in 2023 tied to
5 a future reauthorization of the Pandemic and All-Hazards
6 Preparedness Act or PAHPA. A sunset will provide Congress an
7 opportunity to evaluate the effectiveness of the medical
8 countermeasure PRV program and determine if the program's
9 benefits outweigh its cost. And this sunset date will also allow
10 us to evaluate the program in the broader context of national
11 preparedness during PAHPA reauthorization discussions.

12 In other important areas, such as incentivizing drug
13 development to help children, we recognize the value in periodic
14 program assessment. For example, the Rare Pediatric Disease PRV
15 program, the Best Pharmaceuticals for Children Act, and the
16 Pediatric Research Equity Act all included initial sunset dates.
17 In fact, BPCA and PREA, which offer additional exclusivity to drug
18 manufacturers who conduct pediatric studies were only enacted for
19 five years, and not made permanent until there was significant
20 experience with this incentive.

21 We recognize the importance of evaluating our legislative
22 choices in these situations, and I question how we can justify
23 not taking a similar approach when it comes to medical
24 countermeasure development. So I offer this sunset to insure an

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1 opportunity for lawmakers to assess if this PRV program, if
2 enacted, is improving our ability to protect American citizens
3 from material threats before we permanently extend such a valuable
4 award to drug companies.

5 The need for evaluations rings especially true in the PRV
6 context given the lack of evidence these programs work as
7 intended. As we heard at the May 19th hearing on H.R. 3299, there's
8 been only one study of existing PRV Programs. In this study, GAO
9 found a lack of evidence demonstrating the Rare Pediatric Disease
10 Program was incentivizing new investment in drug R&D. While we
11 do not know if PRV programs are an effective incentive for drug
12 development, we do know the strain these programs place on FDA.
13 We heard from bill supporters that PRV programs are cost-neutral;
14 however, this is not true as they consume significant FDA
15 resources, resources funded by tax dollars.

16 When FDA receives a PRV, it must divert resources from
17 existing work to expedite review of a drug that may under normal
18 circumstances be a lower public health priority. PRVs also reduce
19 the time FDA reviewers have to perform complex drug reviews from
20 10 to six months. We heard from FDA during the May 19th legislative
21 hearing that the fee a company pays when redeeming a PRV does not
22 cover the cost of these expedited drug reviews and, thus, the
23 American taxpayer foots the remaining bill.

24 Now some view a sunset for the medical countermeasure PRV

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1 Program does not take into account the unique nature of medical
2 countermeasure development, and could result in companies not
3 entering this space. And I would, again, note that drug
4 manufacturers already receive considerable financial support
5 from the federal government to develop medical countermeasures.
6 This financial support has been a sufficient incentive for drug
7 companies to develop 89 approved MCMs since 2000. Others suggest
8 that seven years is not long enough to fully assess if the PRV
9 is working in the medical countermeasure space; however, this does
10 not mean we should instead enact a permanent program as after seven
11 years we'll have an understanding of any new investment in medical
12 countermeasure development, including any new entrants.

13 While we do not want to understand if the PRV is an effective
14 incentive for new research and development for medical
15 countermeasures, we must also understand how a third PRV program
16 impacts FDA and the agency's ability to meet agreed upon drug
17 review timelines.

18 I want to go on but my point, Mr. Chairman, is that this
19 amendment is good policy. As lawmakers, I think it's our duty to
20 insure the legislation we enact benefits the American public, and
21 I think a sunset will provide Congress an opportunity to evaluate
22 the medical countermeasure PRV program and determine if extension
23 is in the best interest of national preparedness. I yield back.

24 The Chairman. The gentleman yields back. The Chair would

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1 recognize the gentleman from New York, Mr. Collins.

2 Mr. Collins. I'd like to strike the last word.

3 Sunsetting this PRV Program after seven years would
4 dramatically reduce the impact of the program. A seven-year sunset
5 would only insure that companies that are already in this space
6 would get rewarded for their work, which is important; however,
7 that's not the full purpose of the program.

8 This Priority Review Program as written provides companies
9 to invest in this space in the long term. The uncertainty of a
10 reauthorization provides enough risk to deter companies from
11 going into this space.

12 There are two other Priority Review Voucher Programs, one
13 for Rare Pediatric Diseases, and other for Neglected Tropical
14 Diseases. There's bipartisan support for these programs because
15 we all agree that it's incredibly important that we incentivize
16 innovation in this space. The Neglected Tropical Disease Program
17 does not have a sunset, but the Pediatric Rare Disease PRV Program
18 does.

19 In GAO's review of the Pediatric PRV Program, they were told
20 by patient advocacy groups that a sunset was limiting new research
21 in pediatric diseases. GAO also found that a sunset created
22 ambiguity for industry that, therefore, diminishes the program's
23 appeal. Creating a sunset here would do the exact same thing.

24 We know that these threats are not going away. I do not think

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1 this program should end until we have antidotes for all of them,
2 and that's exactly what this bill does. We need to be prepared,
3 and we need to know we are not prepared right now. We know that
4 the best preparedness for these threats is a stockpile of drugs
5 and vaccines that can be quickly dispensed if and when a threat
6 materializes.

7 I want to thank Mrs. Brooks and Ms. Eshoo for their leadership
8 on this vital piece of legislation. I agree with what Ms. Eshoo
9 said in her opening statement; as Representatives it is our
10 highest responsibility to defend Americans. And I yield back.

11 The Chairman. The gentleman yields back. Other members --
12 the gentlelady from California is recognized for five minutes.

13 Ms. Eshoo. Thank you, Mr. Chairman.

14 I rise in opposition to the amendment, and let me walk members
15 through why. When you look at the amendment that was passed out,
16 the first thing it does is to terminate the authority of the
17 Secretary not to award any Priority Review Vouchers, and then it
18 goes on to put in a review time that is much briefer than what
19 we're requesting.

20 Now, I think that I went through the value of Priority Review
21 Vouchers, why they are important? And I think that members need
22 to appreciate the following facts. A very small number of
23 companies in the private sector engage in the MCM development.
24 This is not big business. You need to understand that. And for

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1 those that do, the only buyer of their products is the United
2 States Federal Government. All right? So we're the buyer, and you
3 know why we are the buyer. We need these products and we want them
4 developed for the protection of the American people.

5 I think that there is a risk of -- let me put it this way.
6 There's hardly a guarantee that there will be a purchase at all,
7 and you've got to take that into consideration. A PRV is
8 essentially a tool, it's adding a tool in the toolkit along with
9 R&D investments to encourage companies to develop these much
10 needed MCMs. So, you know, this is all-there's risk-taking, and
11 you want the private sector to respond. Why we would kill this?
12 I really have trouble getting my head around that.

13 In terms of the timing, let me just point out a few facts
14 about three currently approved products, three currently approved
15 products which would have qualified for PRV and the average time
16 that it took to develop them. A product to treat patients with
17 inhalational anthrax, the time to approval, 13 years. The
18 amendment says stop at seven. A product to treat adult and
19 pediatric patients with inhalational anthrax when alternative
20 therapies are not appropriate, time to approval 12 years. The
21 amendment says seven. A product to treat symptomatic botulism,
22 time to approval 17 years. The amendment says cut it off at seven.

23 I don't know what the rationale of this is. The amendment
24 really represents circling our wagons and shooting at ourselves

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1 because this is all meant to develop what we need and to incent
2 the people that are going to do the research to come up with the
3 product where the federal government is the only buyer of the
4 product. So it's -- there's either a misunderstanding about what
5 this represents, and I'm trying to make it almost conversational
6 so that you understand it, and that you are comfortable with it.

7 The bill includes a very thorough GAO study which is going
8 to give us critical information on how this program is working
9 so we can address fixing it in the future, but if you chop it off
10 and say you're going to stop everything in seven years, then you
11 might as well just fold the tent and say BARDA go away, we're just
12 not going to do this any more, because there has to be -- you have
13 to build in incentives in order to make this thing work.

14 So I appreciate your listening, and I hope I've added
15 something to this debate relative to the amendment because I think
16 this amendment just collapses the whole thing. I think you have
17 to have reviews, but I think that seven years just doesn't work.
18 Thank you, and I yield back.

19 The Chairman. Further amendments, or further members wishing
20 to speak on the amendment? The gentleman is recognized for five
21 minutes. Gene, use the mike.

22 Mr. Green. -- our defense capabilities within the
23 Department of Health and Human Services. I strongly support the
24 intent of the legislation and we tried to work across party lines

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1 and improve and strengthen the bill.

2 What the Pallone Amendment Number 2 would do would give
3 Congress an opportunity to review the success or lack of success
4 instead of having a limitless bill, which is what the current
5 substitute we adopted does. This legislation draws on the recent
6 Blue Ribbon Study Panel of Biodefense and makes targeted reforms
7 to streamline existing programs, enhance coordination between
8 agencies, and develop better data on our preparedness on the
9 ground. However, I also have concerns about the provision to
10 create a new incentive for medical countermeasures, MCMs,
11 development. We tried to reach an agreement but unlike the process
12 we undertook with the 21st Century Cures, the changes we would
13 need to make were not accepted. And, unfortunately, I can't
14 support the bill, but I do support the Pallone Amendment.

15 The amendment in the nature of a substitute that we adopted
16 would establish a new Priority Voucher Program, Review Voucher
17 Program, PRV, that made do little to incentivize novel needed
18 treatments, drain valuable resources at the FDA, and undermine
19 the Neglected Tropical Diseases, the NTDs, and Rare Pediatric
20 Diseases, the PRV Programs by diluting the market value of
21 vouchers. Creating a new PRV Program without addressing loopholes
22 that impede the NTD and PRV program is a missed opportunity.

23 Further, the lack of data demonstrating that two existing
24 PRV Programs are working as intended, or if a new PRV Program for

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1 medical countermeasures will be effective makes it unwise to
2 establish a new program permanently. That's why the Pallone
3 Amendment puts some limit on it. Although, Mrs. Capps has an
4 amendment that we'll see in a few minutes, she has an amendment
5 on the floor, so I'll be introducing it, it would limit it to 12
6 years, which is much better than the Pallone Amendment.

7 The development process, market forces, and role of
8 government in the MCM space is distinct. At the very least,
9 Congress should reserve the ability to exercise oversight on this
10 new incentive rather than authorize it in perpetuity without
11 understanding the necessity or effectiveness. While I appreciate
12 the intent of the provision, I continue to believe that the best
13 way to incentivize MCM development is robust, stable funding
14 similar to the Project Bioshield Special Reserve Fund, the SRV,
15 created in 2004.

16 I support many aspects of this legislation. I thank my
17 colleagues for their commitment for the Biodefense capability.
18 Unfortunately, conversations and commitment to find consensus
19 failed, and that's why I'm supporting the Pallone Amendment to
20 have some limit. But we will see another amendment in a few
21 minutes, and I'll yield back.

22 The Chairman. The gentleman -- -

23 Mr. Green. I'm glad to yield to my colleague from Maryland.

24 Mr. Sarbanes. Thank the gentleman for yielding.

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1 The sunseting strikes me as a reasonable path to take here.
2 I appreciate that there may be some arguments about the impact
3 sunseting could have with respect to the Rare Pediatric Disease
4 development, or Neglected Tropical Disease, but I think it's
5 apples and oranges to compare those to medical countermeasures
6 in terms of the development there. There's evidence that the FDA
7 is doing pretty well in terms of making sure those MCMs are being
8 developed, and even though there may be some examples, and
9 Congresswoman Eshoo has pointed to those, and that's fair to do
10 where development of a particular MCM could take an extended
11 period of time, I would imagine there's also a fair number of --
12 there will be a fair number of opportunities for development of
13 MCMs in a lesser period of time that could offer some examples
14 of whether the PRV process is a useful one with respect to MCMs
15 and do that within the seven-year time frame that's being proposed
16 for sunseting.

17 So if the end goal here with respect to MCMs is to insure
18 that we are developing, and there's plenty of evidence that that
19 is happening without a PRV Program, and I think there will be
20 plenty of examples of how development with a PRV could occur within
21 a seven-year period for us to judge the progress of that, or the
22 potential of that program for further extension. And so for those
23 reasons, it strikes me that that seven-year sunset proposal is
24 a reasonable one. And I yield back.

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1 The Chairman. The gentleman's time is expired. The Chair
2 recognizes the gentlelady from Indiana, Mrs. Brooks.

3 Mrs. Brooks. Thank you, Mr. Chairman. I move to strike the
4 last word.

5 I'd like to remind and actually indicate that I've been
6 informed that of the 13 material threats listed by Department of
7 Homeland Security, in fact, six of the 13 nothing is going on right
8 now. There is no treatment, there is no diagnostic, there is no
9 vaccine, there is nothing. So it is a mistake to presume that
10 companies are working on all of them; they are not. And so if we
11 want to gamble and assume that the terrorists who might be looking
12 at this, or naturally occurring, or if there is a release of one
13 of these products mistakenly, we're going to be taking a chance
14 on what we are prepared for.

15 I appreciate that yes, this is creating a permanent program;
16 however, we worked very hard in listening to the Ranking Member's
17 concerns, and at his request in the amendment in the nature of
18 the substitute we added a new study that was not in the original
19 bill, an incredibly thorough GAO report that wasn't in our
20 original bill that requires an initial assessment of this program
21 after the first 10 years, and then a final report at 16 years.
22 So this does allow future evaluation of the program, which I think
23 would address the Ranking Member's concern. So I don't understand
24 why we would limit our private sector companies and not providing

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1 them this incentive to try to engage in this space in a more robust
2 way than they are.

3 So, effectively, as the Congressman from New York said, once
4 we do have a medical countermeasure for all of these threats, the
5 13 threats, this is going to go away, but we don't have it right
6 now. We just don't. We're not ready. And this isn't just myself
7 and Congresswoman Eshoo saying it, this is what the Biodefense
8 Panel that went around the country and talked to our experts all
9 around the country led by Senator Lieberman and Governor Ridge.
10 And so for that reason, we tried with this GAO report to satisfy
11 your concern about the permanency. We can -- Congress will take
12 a look at this again when GAO does its analysis that's in our bill,
13 and for those reasons I would object to a sunset, and yield back.

14 The Chairman. The gentlelady yields back. The gentlelady
15 from California, Ms. Eshoo.

16 Ms. Eshoo. Thank you, Mr. Chairman.

17 I will present an area that is known for its risk-taking.
18 Everyone knows, I mean the -- I think to every person on the
19 committee, to a person on the committee, I should say, have
20 traveled to my district, so you know that it's in our DNA to be
21 risk-takers. I want to point out that this legislation is not about
22 taking risks. It's the opposite, because this is an area where
23 we can't afford to take risks.

24 I don't know where these numbers are coming from. One is

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1 seven, one is nine, something else, what I idea. We need to have
2 product in our toolbox if, in fact, any of these attacks are made
3 on our country. What are we doing? What are -- I don't understand
4 where this seven years to cut things off because that makes it
5 safer. I think we may be thinking of some other issues, maybe some
6 other drug issues, maybe resentment against drug companies, and
7 previous debates about other issues. That's not what this thing
8 is, and I'm speaking to my own side on this.

9 This is about developing the products that we need. And, yes,
10 if someone applies for a Priority Review Voucher and the FDA
11 reviews it and approves it, and that comes from the list of
12 Homeland Security where they have identified what we need, what
13 is wrong with that? That's airtight, so we should not have any
14 risk in this, as far as I'm concerned. We should leave here feeling
15 very satisfied that we have the tightest case for what this country
16 needs. If, God forbid, there is an attack, we need to be prepared
17 for it. That's what this is. This isn't a favor to me, Anna Eshoo.
18 This isn't some thing that Susan Brooks and I just cooked up. It's
19 based on what has already worked, on what the recommendations of
20 national -- people of national stature and expertise have
21 recommended. That's what this is about.

22 So I would ask you, as uncomfortable as it is, and I think
23 that we have some disputes inside agencies. I think there are some
24 people inside agencies that don't like the idea that they may have

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1 to review and approve something. Well, you know what, I admire
2 them. I have supported them all of my life in terms of their public
3 service, but we're the ones that are elected, they're not in plain
4 English.

5 So I don't support this amendment because I think it's not
6 well-founded. I think it's not well-founded. And to the gentleman
7 from Texas, you never offered to speak to me about anything. And
8 if you had, I would have. So with that, I think -- -

9 Mr. Green. If the gentlelady would yield.

10 Ms. Eshoo. I do have time. Sure.

11 Mr. Green We didn't talk, but I know our Staffs talked and
12 there was no movement in it. And this is something, like I said,
13 we worked on similar legislation over the last couple of years.
14 And my concern is that, you know, we reauthorize legislation all
15 the time, and maybe this amendment is not correct, but maybe the
16 one that Congresswoman Capps has is at 12 years will give that
17 kind of time. But we'll deal with that amendment as it comes up.

18 Ms. Eshoo. Well, reclaiming my time.

19 Mr. Green. Thank you. I yield -- -

20 Ms. Eshoo. It was a -- I know that you said that we didn't
21 come to an agreement, but I want members to know that you didn't
22 seek me out. If you had, I would have been glad to sit down and
23 talk to you. With that, I yield back the balance of my time.

24 The Chairman. The gentlelady yields back. I'd just like to

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1 note, I've just been told from the guy at the end of the hall,
2 end of the dias here that votes on the floor are going to start
3 a little earlier than we suspected, literally in about 10 minutes.
4 So I'd like to finish this debate on this amendment, and do the
5 next one, and get to final. And I think we may have to move the
6 next bill until tomorrow, unless we come back after. You'll just
7 let everybody have that notice. And the gentlelady from Illinois,
8 you have five minutes.

9 Ms. Schakowsky. Thank you. I support the Ranking Member's
10 amendment, but I want to say even if this amendment were to be
11 adopted, I still believe that the underlying legislation is
12 fundamentally flawed.

13 Of course, I agree with my colleagues that we need to address
14 the Biodefense needs, but I am disappointed that this bill fails
15 to make the needed improvements to the Priority Review Program
16 for Tropical Diseases. In fact, it creates an entirely new similar
17 incentive program for drug manufacturers, and we're missing an
18 opportunity to fix the Priority Review Voucher Program for
19 Tropical Diseases with this legislation. Instead, we're doubling
20 down by creating a new program with all the same problems.

21 In a March 29th letter to this committee, concerns were
22 raised by Doctors Without Borders, the TB Alliance, and Drugs for
23 Neglected Disease Initiative, among others, that it is difficult,
24 and sometimes impossible to access drugs approved under the

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1 Tropical Disease Program, and this is because there is no
2 requirement the drug sponsors even make the drug available for
3 purchase. I want to emphasize that, there's no requirement that
4 drug sponsors even make the drug available for purchase.

5 In addition, there is little evidence that Priority Review
6 Voucher Programs are incentivizing drug manufacturers to invest
7 in research and development. Of the three Priority Review Vouchers
8 awarded under the Tropical Disease Program, two were awarded to
9 drugs that had been used for years outside the United States
10 without those drug companies conducting any new research. And this
11 seems counter to the intent of Congress when passing this
12 legislation.

13 When H.R. 3299 was passed by the Health Subcommittee on June
14 7th, I was pleased that it included bipartisan language to fix
15 some of the problems in the Tropical Disease Priority Review
16 Voucher Program. However, today that language has been removed
17 from H.R. 3299, and instead of fixing these problems, the bill
18 completely reverses course by creating a new permanent Priority
19 Review Voucher Program for material threat medical
20 countermeasures.

21 I simply do not agree that we need to provide additional
22 incentives to pharmaceutical companies in order to get them to
23 purchase medical countermeasures. First, there is no evidence
24 that the FDA is not already approving medical countermeasures in

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1 a timely manner. The FDA already has the authority to designate
2 a medical countermeasure for a six-month Priority Review. Since
3 2000, the FDA has approved 89 medical countermeasures and 17
4 supplemental changes to already approved drugs.

5 Additionally, often drug manufactures that produce medical
6 countermeasures receive federal funding for their research and
7 development costs. And once a drug is approved, the federal
8 government spends billions of dollars purchasing these products
9 in order to stockpile them. Despite the substantial benefits, this
10 bill provides even greater incentives to pharmaceutical
11 manufacturers through the creation of a fraud -- a flawed Priority
12 Review Program. Similar to the Tropical Disease Program, Priority
13 Review Vouchers could be awarded for a drug previously approved
14 outside the United States without any requirement that the
15 manufacturers do any research and development additionally.

16 A Priority Review Voucher could be awarded to a drug that
17 does not fulfill any existing need for the federal government.
18 This new incentive program would not expedite FDA's review of
19 these drugs, or the time it would take for a product to come to
20 market. It would only award a drug company a Priority Review
21 Voucher that it could then redeem for any drug of its choosing,
22 or sell to the highest bidder.

23 These vouchers are incredibly lucrative for pharmaceutical
24 companies. In August 2015, a voucher was sold for \$350 million.

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1 We've also seen people like Martin Shkreli acquire drug companies
2 because those companies own a drug eligible for a Tropical Disease
3 Priority Review Voucher. In the case of Shkreli, his company then
4 announced that once the government awarded it a Priority Review
5 Voucher, they intended to make this lifesaving drug so expensive
6 that it would put it out of reach of almost all that need it.

7 This proves how profitable these vouchers are, and how easily
8 they can be exploited. Clearly, we need to be thoughtful in when
9 and how we award Priority Review Vouchers. I don't believe that
10 H.R. 3299, even with this amendment, frankly, which I do support,
11 takes the necessary steps to reform the existing Priority Review
12 Voucher Program. Instead, it creates an entire new incentive
13 program that we expect will have many of the very same problems.
14 I yield back.

15 The Chairman. The gentlelady's time is expired. Other
16 members wishing to speak on the amendment? The gentleman from --
17 Mr. Schrader. The gentleman is recognized for five minutes.

18 Mr. Schrader. Yes. I share some of the concerns of the
19 gentlelady from Illinois. And I'm a little concerned, or surprised
20 that the committee as a whole is not concerned about the open-ended
21 nature of the Priority Review process. I think the Voucher Program
22 is a good one. I think it has great value in tailored situations.
23 This bill, unfortunately, does not get to that. I think the
24 subcommittee that worked on this bill is a little outraged. The

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1 final bill does not represent anything that we worked on in the
2 subcommittee.

3 If this is truly regular order, I would hope that whether
4 you're Republican or Democrat, you want the process to reflect
5 the hard work of the subcommittee, and the members that are on
6 this thing.

7 The bill needs to be tailored. I mean, the reason, with all
8 due deference to the gentlelady from Indiana, the reason some of
9 these products aren't listed is there's already treatment for
10 them. Simple antibiotics take care of a lot of the drugs, excuse
11 me, the conditions that are on the list. For anthrax we also have
12 AVA vaccine, we've got anthrax immunoglobulin, smallpox we've got
13 MBA vaccine, botulism, we've got the antitoxin there. For
14 radionuclear stuff, potassium iodide, Neupogen, others, nerve
15 agent issues we've got midazolam. Do we want to continue to give
16 money to different companies, taxpayer money, when there's
17 already treatment available?

18 I think that a sunset is a good idea. That doesn't mean the
19 program goes away. If we think this program has value, we
20 reauthorize it. My colleagues on the other side of the aisle and
21 conservative Democrats like me, we'd like to reevaluate how we're
22 spending our money on our regular basis. And this is not what this
23 bill does. So I'm not opposed to Priority Review Vouchers. I mean,
24 I'm working on a bill with Mr. Bilirakis, one where there's no

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1 other agent, where Shkreli, whatever that guy's name is, you buy
2 up a company, you rip off the consumer and put people's health
3 at risk. That's not appropriate. That's where this program goes
4 to.

5 So I'm very concerned that, unfortunately, we're getting way
6 off of what the original Tropical Disease Program was about. We
7 need to set back, reevaluate, allow these programs to sunset and,
8 frankly, look at a bill that reflects what the subcommittee
9 actually tried to bring to the floor. I yield back.

10 Ms. DeGette. Will the gentleman yield?

11 Mr. Schrader. Yes, certainly.

12 Ms. DeGette. I just want to add, I agree. I actually think
13 that both of the sponsors on this bill have worked very hard, and
14 I also know that the Staffs have been trying to negotiate some
15 of these issues. And I want to associate myself with a lot of what
16 my colleagues on this side of the aisle have said about making
17 sure that we do this right, making sure that the PRV programs are
18 actually used in a targeted way.

19 I think that a sunset could be a really good idea to make
20 sure that happens. I've heard that at least 10, and as many as
21 20 years can be taken to develop these countermeasures, and so
22 I'm not -- frankly, this is just me speaking. I'm not sure a
23 seven-year period is the right amount. I know that Mr. Green is
24 going to offer Mrs. Capps' amendment for 12 years. I kind of feel

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1 like we're just throwing stuff up. I do think that a sunset period
2 would be good. I don't have the magic number of what that would
3 be. And I would hope since we're planning to go on recess this
4 week that we could -- irrespective of what happens, that we could
5 all work together over the August recess so when we bring this
6 bill to the floor, it's something that we can all support as a
7 committee, Democrats and Republicans, because I do think it's a
8 very bipartisan issue, and I think it's an important bill. And
9 I yield back to Mr. Schrader.

10 Mr. Schrader. I yield back my time, Mr. Chairman. Thank you.

11 The Chairman. The gentleman's time is expired. Other members
12 wishing to speak on the amendment? Oh, the gentlelady from
13 California has a unanimous consent request.

14
15 Ms. Eshoo. Mr. Chairman, I have a unanimous consent request
16 to place two letters -- -

17 The Chairman. Without objection.

18 Ms. Eshoo. -- that I failed to do earlier.

19 The Chairman. Thank you.

20 Now, are there other members wishing to speak on the
21 amendment? Seeing none, the vote is on the amendment. Gentleman
22 from New Jersey, roll call is requested. The Clerk will call the
23 tally.

24 The Clerk. Mr. Barton.

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1 [No response.]

2 The Clerk. Mr. Whitfield.

3 Mr. Whitfield. No.

4 The Clerk. Mr. Whitfield votes no.

5 Mr. Shimkus.

6 Mr. Shimkus. No.

7 The Clerk. Mr. Shimkus votes no.

8 Mr. Pitts.

9 Mr. Pitts. No.

10 The Clerk. Mr. Pitts votes no.

11 Mr. Walden.

12 Mr. Walden. No.

13 The Clerk. Mr. Walden votes no.

14 Mr. Murphy.

15 Mr. Murphy. No.

16 The Clerk. Mr. Murphy votes no.

17 Mr. Burgess.

18 Mr. Burgess. No.

19 The Clerk. Mr. Burgess votes no.

20 Mrs. Blackburn.

21 Mrs. Blackburn. No.

22 The Clerk. Mrs. Blackburn votes no.

23 Mr. Scalise.

24 Mr. Scalise. No.

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1 The Clerk. Mr. Scalise votes no.

2 Mr. Latta.

3 Mr. Latta. No.

4 The Clerk. Mr. Latta votes no.

5 Mrs. McMorris Rodgers.

6 [No response.]

7 The Clerk. Mr. Harper.

8 Mr. Harper. No.

9 The Clerk. Mr. Harper votes no.

10 Mr. Lance.

11 Mr. Lance. No.

12 The Clerk. Mr. Lance votes no.

13 Mr. Guthrie.

14 Mr. Guthrie. No.

15 The Clerk. Mr. Guthrie votes no.

16 Mr. Olson.

17 Mr. Olson. No.

18 The Clerk. Mr. Olson votes no.

19 Mr. McKinley.

20 Mr. McKinley. No.

21 The Clerk. Mr. McKinley votes no.

22 Mr. Pompeo.

23 Mr. Pompeo. No.

24 The Clerk. Mr. Pompeo votes no.

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1 Mr. Kinzinger.

2 Mr. Kinzinger. No.

3 The Clerk. Mr. Kinzinger votes no.

4 Mr. Griffith.

5 Mr. Griffith. No.

6 The Clerk. Mr. Griffith votes no.

7 Mr. Bilirakis.

8 Mr. Bilirakis. No.

9 The Clerk. Mr. Bilirakis votes no.

10 Mr. Johnson.

11 Mr. Johnson. No.

12 The Clerk. Mr. Johnson votes no.

13 Mr. Long.

14 Mr. Long. No.

15 The Clerk. Mr. Long votes no.

16 Mrs. Ellmers.

17 Mrs. Ellmers. No.

18 The Clerk. Mrs. Ellmers votes no.

19 Mr. Bucshon.

20 Mr. Bucshon. No.

21 The Clerk. Mr. Bucshon votes no.

22 Mr. Flores.

23 Mr. Flores. No.

24 The Clerk. Mr. Flores votes no.

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1 Mrs. Brooks.

2 Mrs. Brooks. No.

3 The Clerk. Mrs. Brooks votes no.

4 Mr. Mullin.

5 Mr. Mullin. No.

6 The Clerk. Mr. Mullin votes no.

7 Mr. Hudson.

8 Mr. Hudson. No.

9 The Clerk. Mr. Hudson votes no.

10 Mr. Collins.

11 Mr. Collins. No.

12 The Clerk. Mr. Collins votes no.

13 Mr. Cramer.

14 Mr. Cramer. No.

15 The Clerk. Mr. Cramer votes no.

16 Mr. Pallone.

17 Mr. Pallone. Aye.

18 The Clerk. Mr. Pallone votes aye.

19 Mr. Rush.

20 Mr. Rush. Aye.

21 The Clerk. Mr. Rush votes aye.

22 Ms. Eshoo.

23 Ms. Eshoo. No.

24 The Clerk. Ms. Eshoo votes no.

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1 Mr. Engel.

2 Mr. Engel. Aye.

3 The Clerk. Mr. Engel votes aye.

4 Mr. Green.

5 Mr. Green. Aye.

6 The Clerk. Mr. Green votes aye.

7 Ms. DeGette.

8 Ms. DeGette. No.

9 The Clerk. Ms. DeGette votes no.

10 Mrs. Capps.

11 [No response.]

12 The Clerk. Mr. Doyle.

13 Mr. Doyle. No.

14 The Clerk. Mr. Doyle votes no.

15 Ms. Schakowsky.

16 Ms. Schakowsky. Aye.

17 The Clerk. Ms. Schakowsky votes aye.

18 Mr. Butterfield.

19 Mr. Butterfield. No.

20 The Clerk. Mr. Butterfield votes no.

21 Ms. Matsui.

22 Ms. Matsui. No.

23 The Clerk. Ms. Matsui votes no.

24 Ms. Castor.

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1 Ms. Castor. Aye.

2 The Clerk. Ms. Castor votes aye.

3 Mr. Sarbanes.

4 Mr. Sarbanes. Aye.

5 The Clerk. Mr. Sarbanes votes aye.

6 Mr. McNerney.

7 Mr. McNerney. No.

8 The Clerk. Mr. McNerney votes no.

9 Mr. Welch.

10 Mr. Welch. Aye.

11 The Clerk. Mr. Welch votes aye.

12 Mr. Lujan.

13 Mr. Lujan. No.

14 The Clerk. Mr. Lujan votes no.

15 Mr. Tonko.

16 Mr. Tonko. Aye.

17 The Clerk. Mr. Tonko votes aye.

18 Mr. Yarmuth.

19 Mr. Yarmuth. Aye.

20 The Clerk. Mr. Yarmuth votes aye.

21 Ms. Clarke.

22 Ms. Clarke. Aye.

23 The Clerk. Ms. Clarke votes aye.

24 Mr. Loeb sack.

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1 Mr. Loeb sack. Aye.

2 The Clerk. Mr. Loeb sack votes aye.

3 Mr. Schrader.

4 Mr. Schrader. Aye.

5 The Clerk. Mr. Schrader votes aye.

6 Mr. Kennedy.

7 Mr. Kennedy. Aye.

8 The Clerk. Mr. Kennedy votes aye.

9 Mr. Cardenas.

10 Mr. Cardenas. No.

11 The Clerk. Mr. Cardenas votes no.

12 Chairman Upton.

13 Chairman Upton. Votes no.

14 The Clerk. Chairman Upton votes no.

15 The Chairman. Other members wishing to cast a vote? Mr.
16 Barton.

17 Mr. Barton. No.

18 The Clerk. Mr. Barton votes no.

19 The Chairman. Any other members wishing to change their vote
20 or cast a vote? Seeing none, the Clerk will report the tally.

21 The Clerk. Mr. Chairman, on that vote there were 14 ayes,
22 38 nos.

23 The Chairman. Fourteen ayes, 38 nos, the amendment is not
24 agreed to.

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1 Are there further amendments to the bill? The gentleman from
2 Texas, Mr. Green, has an amendment at the desk.

3 Mr. Green. There is an amendment at the desk, Mr. Chairman,
4 that I agreed to carry for colleague, Mrs. Capps, who's on the
5 floor of the House.

6 The Chairman. The Clerk will report the title of the
7 amendment.

8 [The Amendment offered by Mrs. Capps follows:]

9

10 *****INSERT 19*****

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1 The Clerk. Amendment to the amendment in the nature of a
2 substitute to H.R. 3299 offered by Mr. Green for Mrs. Capps.

3 The Chairman. And the amendment will be considered as read.
4 The Staff will distribute the amendment, and the gentleman is
5 given five minutes in support of the amendment.

6 Mr. Green. Thank you, Mr. Chairman.

7 I appreciate what the authors of the legislation are trying
8 to achieve with H.R. 3299, but I also understand the concerns
9 raised by the Ranking Member, the FDA, and others on our committee
10 about the effectiveness and utility of Priority Review Vouchers.
11 Priority Review Vouchers particularly heighten when you consider
12 that the program being created by this bill would be a permanent
13 program, and that there are also concerns that the language may
14 not be tight enough to insure that the products moved through this
15 pathway will actually meet the needs of the federal government.

16 The truth is, if the jury is still out on the effectiveness
17 of the PRV Programs as a whole. There's great debate as to whether
18 PRV Programs are effective at getting treatments to those who need
19 them, or that they truly incentivize new investment in these
20 areas.

21 As we have seen in the Tropical Disease Program, PRV Program,
22 sometimes there's novel pathways with unintended consequences and
23 loopholes that we need to have the chance to address. Given that
24 medical countermeasures are products developed for purchase by

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1 the federal government it is critical that the program works the
2 way it was intended to so that we get the products we need, and
3 the taxpayers aren't on the hook for those we don't.

4 As such, I do believe it's important that we be required to
5 revisit this program down the road, if it becomes law. Some offered
6 a seven-year time frame, that wasn't enough to gather all the data.
7 Others have proposed 17 years, but that may be too long a window
8 to insure the problems are addressed because the taxpayers on the
9 hook. This amendment splits the difference and would sunset the
10 program after 12 years. And, you know, Congress can always revisit
11 it, but it would insure transparency by ordering a preliminary
12 GAO report to be made available every seven years, while a more
13 thorough report is released a year before the reauthorization.

14 It's important to note that nothing in the amendment would
15 preclude Congress from reauthorizing the program beyond the
16 12-year window. What it would do is to insure that Congress review
17 the MCM PRV Program after more information on the effectiveness
18 of this and the other PRV Programs are available. And it would
19 provide a time frame for addressing any potential unintended
20 consequences or loopholes that are found in the program once it's
21 operational. And I recognize that some may think it's too long
22 enough, but other think it's too long a window, but this important
23 amount of time should be sufficient to gauge the workings of the
24 program, as well as get data from the other existing PRV Programs

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1 to help inform Congress for reauthorization.

2 This amendment, I think, is a commonsense addition to this
3 legislation, and I urge my colleagues to support it. And I'll yield
4 back my time.

5 The Chairman. The gentleman yields back in an effort to save
6 time, and I'll yield myself to strike the last word. We don't
7 support the sunset after 10 years, and I would urge my colleagues,
8 12. They don't support 10, either; 12 years. And I would urge my
9 Republican colleagues and Democrat colleagues to vote no, and I'll
10 yield back.

11 Other members wishing to speak on the amendment? The
12 gentleman from New Jersey, five minutes.

13 Mr. Pallone. Thank you, Mr. Chairman.

14 As I stated previously, Congress found it appropriate to
15 sunset programs intended to incentivize development of drugs to
16 treat children so that we have the opportunity to evaluate whether
17 an incentive program we created worked. And I fail to understand
18 how we justify a different approach in the medical countermeasure
19 space, and how an opportunity to evaluate if a program is
20 successful before permanently authorizing it is not sound
21 governance.

22 The Best Pharmaceuticals for Children Act, and the Pediatric
23 Research Equity Act, which offered additional exclusivity to drug
24 manufacturers who conduct Pediatric studies were initially

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1 enacted for five years. Both programs were reauthorized for an
2 additional five years multiple times before we made the programs
3 permanent in 2012. And these sunset dates allowed us to evaluate
4 the effectiveness of these programs as an incentive,
5 understanding the impact on the FDA and understanding if the
6 benefits of the program are worth the cost to the American people.

7 We also included an initial cap and later a sunset for the
8 Rare Pediatric PRV Program. The GAO study of this program, the
9 only study to date of any PRV program, found little evidence that
10 the program was incentivizing new investment in drug research and
11 development to treat Rare Pediatric Diseases. Given the lack of
12 understanding about whether PRV Programs are incentivizing new
13 investment versus serving as a windfall to drug manufacturers
14 already developing, I strongly urge my colleagues to consider if
15 a permanent program is sensible policy.

16 While a 12-year sunset is longer than I believe necessary,
17 I support this amendment. It will prevent an unproven program from
18 being enacted permanently without evidence that it works. A
19 12-year sunset will allow us to assess if the medical
20 countermeasures PRV Program is effective, and if there are
21 unintended consequences before permanently authorizing a program
22 that gives such a valuable award to drug companies at the expense
23 of FDA's ability to expedite review of other important drugs to
24 the American people. I yield back.

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1 The Chairman. Other members wishing to speak? The gentlelady
2 from California is recognized.

3 Ms. Eshoo. Thank you, Mr. Chairman. I move to strike the last
4 word.

5 First, I want to thank the Ranking Member for talking about
6 and mentioning the two laws, bills I both wrote, the Better
7 Pharmaceutical for Children's Act, as well as the other
8 legislation. The difference between those and the Priority Review
9 mechanisms that are in the laws that Mr. Pallone just raised, and
10 I wrote, is that those -- the drugs that we're talking about in
11 this program are not marketed. In the Children's Pediatric bill,
12 the Better Pharmaceutical Act bill, it's a different story for
13 those. So I think that there is a big difference between the two,
14 and I think members need to understand that and have an
15 appreciation of it.

16 On the language that's in the amendment, the 15 years was
17 structured in the following way. In the legislation that
18 Congresswoman Brooks and I are sponsoring, you know that we called
19 for the GAO study. That GAO study comes out in 16 years from the
20 enactment of the bill, and that's why 15 was in the bill, because
21 of the GAO study. So just so that you understand that there's a
22 linkage, and that we're consistent about what we're doing. Some
23 like it, some don't, but that's the reason for it. And I yield
24 back the balance of my time.

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1 The Chairman. The gentlelady yields back. Other members
2 wishing to speak on the amendment? Seeing none -- a recorded vote
3 is asked for. Note votes have started on the House floor so we
4 will hurry this roll call.

5 The Clerk. Mr. Barton.

6 Mr. Barton. No.

7 The Clerk. Mr. Barton votes no.

8 Mr. Whitfield.

9 Mr. Whitfield. No.

10 The Clerk. Mr. Whitfield votes no.

11 Mr. Shimkus.

12 Mr. Shimkus. No.

13 The Clerk. Mr. Shimkus votes no.

14 Mr. Pitts.

15 Mr. Pitts. No.

16 The Clerk. Mr. Pitts votes no.

17 Mr. Walden.

18 Mr. Walden. No.

19 The Clerk. Mr. Walden votes no.

20 Mr. Murphy.

21 Mr. Murphy. No.

22 The Clerk. Mr. Murphy votes no.

23 Mr. Burgess.

24 Mr. Burgess. No.

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1 The Clerk. Mr. Burgess votes no.

2 Mrs. Blackburn.

3 Mrs. Blackburn. No.

4 The Clerk. Mrs. Blackburn votes no.

5 Mr. Scalise.

6 [No response.]

7 The Clerk. Mr. Latta.

8 Mr. Latta. No.

9 The Clerk. Mr. Latta votes no.

10 Mrs. McMorris Rodgers.

11 [No response.]

12 The Clerk. Mr. Harper.

13 Mr. Harper. No.

14 The Clerk. Mr. Harper votes no.

15 Mr. Lance.

16 Mr. Lance. No.

17 The Clerk. Mr. Lance votes no.

18 Mr. Guthrie.

19 Mr. Guthrie. No.

20 The Clerk. Mr. Guthrie votes no.

21 Mr. Olson.

22 Mr. Olson. No.

23 The Clerk. Mr. Olson votes no.

24 Mr. McKinley.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. McKinley. No.

2 The Clerk. Mr. McKinley votes no.

3 Mr. Pompeo.

4 Mr. Pompeo. No.

5 The Clerk. Mr. Pompeo votes no.

6 Mr. Kinzinger.

7 Mr. Kinzinger. No.

8 The Clerk. Mr. Kinzinger votes no.

9 Mr. Griffith.

10 Mr. Griffith. No.

11 The Clerk. Mr. Griffith votes no.

12 Mr. Bilirakis.

13 Mr. Bilirakis. No.

14 The Clerk. Mr. Bilirakis votes no.

15 Mr. Johnson.

16 Mr. Johnson. No.

17 The Clerk. Mr. Johnson votes no.

18 Mr. Long.

19 Mr. Long. No.

20 The Clerk. Mr. Long votes no.

21 Mrs. Ellmers.

22 Mrs. Ellmers. No.

23 The Clerk. Mrs. Ellmers votes no.

24 Mr. Bucshon.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Bucshon. No.

2 The Clerk. Mr. Bucshon votes no.

3 Mr. Flores.

4 Mr. Flores. No.

5 The Clerk. Mr. Flores votes no.

6 Mrs. Brooks.

7 Mrs. Brooks. No.

8 The Clerk. Mrs. Brooks votes no.

9 Mr. Mullin.

10 Mr. Mullin. No.

11 The Clerk. Mr. Mullin votes no.

12 Mr. Hudson.

13 Mr. Hudson. No.

14 The Clerk. Mr. Hudson votes no.

15 Mr. Collins.

16 Mr. Collins. No.

17 The Clerk. Mr. Collins votes no.

18 Mr. Cramer.

19 Mr. Cramer. No.

20 The Clerk. Mr. Cramer votes no.

21 Mr. Pallone.

22 Mr. Pallone. Aye.

23 The Clerk. Mr. Pallone votes aye.

24 Mr. Rush.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Rush. Aye.

2 The Clerk. Mr. Rush votes aye.

3 Ms. Eshoo.

4 Ms. Eshoo. No.

5 The Clerk. Ms. Eshoo votes no.

6 Mr. Engel.

7 Mr. Engel. Aye.

8 The Clerk. Mr. Engel votes aye.

9 Mr. Green.

10 Mr. Green. Aye.

11 The Clerk. Mr. Green votes aye.

12 Ms. DeGette.

13 Ms. DeGette. Aye.

14 The Clerk. Ms. DeGette votes aye.

15 Mrs. Capps.

16 [No response.]

17 The Clerk. Mr. Doyle.

18 Mr. Doyle. Aye.

19 The Clerk. Mr. Doyle votes aye.

20 Ms. Schakowsky.

21 Ms. Schakowsky. Yes.

22 The Clerk. Ms. Schakowsky votes aye.

23 Mr. Butterfield.

24 Mr. Butterfield. No.

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1 The Clerk. Mr. Butterfield votes no.

2 Ms. Matsui.

3 Ms. Matsui. No.

4 The Clerk. Ms. Matsui votes no.

5 Ms. Castor.

6 Ms. Castor. No.

7 The Clerk. Ms. Castor votes no.

8 Mr. Sarbanes.

9 Mr. Sarbanes. Aye.

10 The Clerk. Mr. Sarbanes votes aye.

11 Mr. McNerney.

12 Mr. McNerney. Aye.

13 The Clerk. Mr. McNerney votes aye.

14 Mr. Welch.

15 Mr. Welch. Aye.

16 The Clerk. Mr. Welch votes aye.

17 Mr. Lujan.

18 Mr. Lujan. Aye.

19 The Clerk. Mr. Lujan votes aye.

20 Mr. Tonko.

21 Mr. Tonko. Aye.

22 The Clerk. Mr. Tonko votes aye.

23 Mr. Yarmuth.

24 Mr. Yarmuth. Aye.

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1 The Clerk. Mr. Yarmuth votes aye.

2 Ms. Clarke.

3 Ms. Clarke. Aye.

4 The Clerk. Ms. Clarke votes aye.

5 Mr. Loeb sack.

6 Mr. Loeb sack. Aye.

7 The Clerk. Mr. Loeb sack votes aye.

8 Mr. Schrader.

9 Mr. Schrader. Aye.

10 The Clerk. Mr. Schrader votes aye.

11 Mr. Kennedy.

12 Mr. Kennedy. Aye.

13 The Clerk. Mr. Kennedy votes aye.

14 Mr. Cardenas.

15 Mr. Cardenas. No.

16 The Clerk. Mr. Cardenas votes no.

17 Chairman Upton.

18 Chairman Upton. Votes no.

19 The Clerk. Chairman Upton votes no.

20 The Chairman. Those wishing to vote, change your vote? Seeing
21 none, the Clerk will report the tally.

22 The Clerk. Mr. Chairman, on that vote there were 18 ayes,
23 34 nos.

24 The Chairman. Seventeen ayes, 24 nos, the amendment is not

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1 agreed to.

2 Are there further amendments to the bill? Seeing none, the
3 vote occurs on final passage. Roll call is requested. Tell the
4 members we'll come back tomorrow for the last bill at 10:00
5 tomorrow. So the Clerk will call the tally for final passage.

6 The Clerk. Mr. Barton.

7 Mr. Barton. Aye.

8 The Clerk. Mr. Baton votes aye.

9 Mr. Whitfield.

10 Mr. Whitfield. Aye.

11 The Clerk. Mr. Whitfield votes aye.

12 Mr. Shimkus.

13 Mr. Shimkus. Aye.

14 The Clerk. Mr. Shimkus votes aye.

15 Mr. Pitts.

16 Mr. Pitts. Aye.

17 The Clerk. Mr. Pitts votes aye.

18 Mr. Walden.

19 Mr. Walden. Aye.

20 The Clerk. Mr. Walden votes aye.

21 Mr. Murphy.

22 Mr. Murphy. Aye.

23 The Clerk. Mr. Murphy votes aye.

24 Mr. Burgess.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Burgess. Aye.

2 The Clerk. Mr. Burgess votes aye.

3 Mrs. Blackburn.

4 Mrs. Blackburn. Aye.

5 The Clerk. Mrs. Blackburn votes aye.

6 Mr. Scalise.

7 [No response.]

8 The Clerk. Mr. Latta.

9 Mr. Latta. Aye.

10 The Clerk. Mr. Latta votes aye.

11 Mrs. McMorris Rodgers.

12 [No response.]

13 The Clerk. Mr. Harper.

14 Mr. Harper. Aye.

15 The Clerk. Mr. Harper votes aye.

16 Mr. Lance.

17 Mr. Lance. Aye.

18 The Clerk. Mr. Lance votes aye.

19 Mr. Guthrie.

20 Mr. Guthrie. Aye.

21 The Clerk. Mr. Guthrie votes aye.

22 Mr. Olson.

23 Mr. Olson. Aye.

24 The Clerk. Mr. Olson votes aye.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. McKinley.

2 Mr. McKinley. Aye.

3 The Clerk. Mr. McKinley votes aye.

4 Mr. Pompeo.

5 Mr. Pompeo. Aye.

6 The Clerk. Mr. Pompeo votes aye.

7 Mr. Kinzinger.

8 Mr. Kinzinger. Aye.

9 The Clerk. Mr. Kinzinger votes aye.

10 Mr. Griffith.

11 Mr. Griffith. Aye.

12 The Clerk. Mr. Griffith votes aye.

13 Mr. Bilirakis.

14 Mr. Bilirakis. Aye.

15 The Clerk. Mr. Bilirakis votes aye.

16 Mr. Johnson.

17 Mr. Johnson. Aye.

18 The Clerk. Mr. Johnson votes aye.

19 Mr. Long.

20 Mr. Long. Aye.

21 The Clerk. Mr. Long votes aye.

22 Mrs. Ellmers.

23 Mrs. Ellmers. Aye.

24 The Clerk. Mrs. Ellmers votes aye.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Bucshon.

2 Mr. Bucshon. Aye.

3 The Clerk. Mr. Bucshon votes aye.

4 Mr. Flores.

5 Mr. Flores. Aye.

6 The Clerk. Mr. Flores votes aye.

7 Mrs. Brooks.

8 Mrs. Brooks. Aye.

9 The Clerk. Mrs. Brooks votes aye.

10 Mr. Mullin.

11 Mr. Mullin. Aye.

12 The Clerk. Mr. Mullin votes aye.

13 Mr. Hudson.

14 Mr. Hudson. Aye.

15 The Clerk. Mr. Hudson votes aye.

16 Mr. Collins.

17 Mr. Collins. Aye.

18 The Clerk. Mr. Collins votes aye.

19 Mr. Cramer.

20 Mr. Cramer. Aye.

21 The Clerk. Mr. Cramer votes aye.

22 Mr. Pallone.

23 Mr. Pallone. No.

24 The Clerk. Mr. Pallone votes no.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Rush.

2 Mr. Rush. No.

3 The Clerk. Mr. Rush votes no.

4 Ms. Eshoo.

5 Ms. Eshoo. Aye.

6 The Clerk. Ms. Eshoo votes aye.

7 Mr. Engel.

8 Mr. Engel. Aye.

9 The Clerk. Mr. Engel votes aye.

10 Mr. Green.

11 Mr. Green. No.

12 The Clerk. Mr. Green votes no.

13 Ms. DeGette.

14 Ms. DeGette. No.

15 The Clerk. Ms. DeGette votes no.

16 Mrs. Capps.

17 [No response.]

18 The Clerk. Mr. Doyle.

19 Mr. Doyle. Aye.

20 The Clerk. Mr. Doyle votes aye.

21 Ms. Schakowsky.

22 Ms. Schakowsky. No.

23 The Clerk. Ms. Schakowsky votes no.

24 Mr. Butterfield.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Butterfield. Aye.

2 The Clerk. Mr. Butterfield votes aye.

3 Ms. Matsui.

4 Ms. Matsui. Aye.

5 The Clerk. Ms. Matsui votes aye.

6 Ms. Castor.

7 Ms. Castor. No.

8 The Clerk. Ms. Castor votes no.

9 Mr. Sarbanes.

10 Mr. Sarbanes. No.

11 The Clerk. Mr. Sarbanes votes no.

12 Mr. McNerney.

13 Mr. McNerney. Aye.

14 The Clerk. Mr. McNerney votes aye.

15 Mr. Welch.

16 Mr. Welch. No.

17 The Clerk. Mr. Welch votes no.

18 Mr. Lujan.

19 Mr. Lujan. No.

20 The Clerk. Mr. Lujan votes no.

21 Mr. Tonko.

22 Mr. Tonko. No.

23 The Clerk. Mr. Tonko votes no.

24 Mr. Yarmuth.

This is an unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker.

1 Mr. Yarmuth. No.

2 The Clerk. Mr. Yarmuth votes no.

3 Ms. Clarke.

4 Ms. Clarke. No.

5 The Clerk. Ms. Clarke votes no.

6 Mr. Loeb sack.

7 Mr. Loeb sack. No.

8 The Clerk. Mr. Loeb sack votes no.

9 Mr. Schrader.

10 Mr. Schrader. No.

11 The Clerk. Mr. Schrader votes no.

12 Mr. Kennedy.

13 Mr. Kennedy. No.

14 The Clerk. Mr. Kennedy votes no.

15 Mr. Cardenas.

16 Mr. Cardenas. Aye.

17 The Clerk. Mr. Cardenas votes aye.

18 Chairman Upton.

19 Chairman Upton. Votes aye.

20 The Clerk. Chairman Upton votes aye.

21 The Chairman. Other members wishing to change your vote, or
22 cast a vote? Seeing none, the Clerk will report the tally.

23 The Clerk. Mr. Chairman, on that vote there were 36 ayes,
24 and 15 nos.

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1 The Chairman. Thirty-six ayes, 15 nos, the bill as amended
2 is passed, and the committee stands in recess until 10:00
3 tomorrow.

4 [Whereupon, at 9:29 p.m., the committee was adjourned.]