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MARKUP OF:

H.R. 338, TO PROMOTE A 21ST CENTURY ENERGY AND MANUFACTURING WORKFORCE;

H.R. 627, STREAMLINING ENERGY EFFICIENCY FOR SCHOOLS ACT OF 2017;

H.R. 723, ENERGY SAVINGS THROUGH PUBLIC-PRIVATE PARTNERSHIPS ACT OF 2017;

H.R. 1109, TO AMEND SECTION 203 OF THE FEDERAL POWER ACT;

H.R. 446, TO EXTEND THE DEADLINE FOR COMMENCEMENT OF CONSTRUCTION OF A HYDROELECTRIC PROJECT (FLANNAGAN, VIRGINIA);

H.R. 447, TO EXTEND THE DEADLINE FOR COMMENCEMENT OF CONSTRUCTION OF A HYDROELECTRIC PROJECT (GATHRIGHT, VIRGINIA);

H.R. 951, TO EXTEND THE DEADLINE FOR COMMENCEMENT OF CONSTRUCTION OF A HYDROELECTRIC PROJECT (W. KERR SCOTT, NORTH CAROLINA);

H.R. 2122, TO REINSTATE AND EXTEND THE DEADLINE FOR COMMENCEMENT OF CONSTRUCTION OF A HYDROELECTRIC PROJECT INVOLVING JENNINGS RANDOLPH DAM (WEST VIRGINIA);

H.R. 2274, HYDROPOWER PERMIT EXTENSION (HYPE) ACT;

H.R. 2292, TO EXTEND A PROJECT OF THE FEDERAL ENERGY REGULATORY COMMISSION INVOLVING THE CANNONSVILLE DAM;

H.R. 2457, J. BENNETT JOHNSTON WATERWAY HYDROPOWER EXTENSION ACT OF 2017;

H.R. 1222, CONGENITAL HEART FUTURES REAUTHORIZATION ACT OF 2017 (AS AMENDED BY THE SUBCOMMITTEE ON HEALTH ON MAY 18, 2017);

H.R. 1492, MEDICAL CONTROLLED SUBSTANCES TRANSPORTATION ACT OF 2017;

H.R. 2410 SICKLE CELL DISEASE RESEARCH, SURVEILLANCE, PREVENTION, AND TREATMENT ACT OF 2017; AND

H.R. 2430, FDA REAUTHORIZATION ACT OF 2017 (AS AMENDED BY THE SUBCOMMITTEE ON HEALTH ON MAY 18, 2017).

WEDNESDAY, JUNE 7, 2017

House of Representatives

Committee on Energy and Commerce

Washington, D.C.

The committee met, pursuant to call, at 10:00 a.m., in Room 2123 Rayburn House Office Building, Hon. Greg Walden [chairman of the committee] presiding.

Members present: Representatives Walden, Barton, Upton, Shimkus, Murphy, Burgess, Blackburn, Scalise, Latta, McMorris Rodgers, Harper, Lance, Guthrie, Olson, McKinley, Kinzinger, Griffith, Bilirakis, Johnson, Long, Bucshon, Flores, Brooks,

Mullin, Hudson, Collins, Cramer, Walberg, Walters, Costello, Carter, Pallone, Rush, Eshoo, Green, DeGette, Doyle, Schakowsky, Butterfield, Matsui, Castor, Sarbanes, McNerney, Welch, Lujan, Tonko, Clarke, Loebsack, Schrader, Kennedy, Cardenas, Ruiz, Peters, and Dingell.

Staff present: Mike Bloomquist, Deputy Staff Director; Elena Brennan, Legislative Clerk, Oversight and Investigations; Adam Buckalew, Professional Staff, Health; Karen Christian, General Counsel; Jordan Davis, Director of Policy and External Affairs; Paul Edattel, Chief Counsel, Health; Wyatt Ellertson, Research Associate, Energy/Environment; Blair Ellis, Digital Coordinator/Press Secretary; Adam Fromm, Director of Outreach and Coalitions; Giulia Giannangeli, Legislative Clerk, Digital Commerce and Consumer Protection/Environment; Caleb Graff, Professional Staff Member, Health; Jay Gulshen, Legislative Clerk, Health; Tom Hassenboehler, Chief Counsel, Energy/Environment; Zach Hunter, Director of Communications; A.T. Johnston, Senior Policy Advisor/Professional Staff, Energy/Environment; Peter Kielty, Deputy General Counsel; Ben Lieberman, Senior Counsel, Energy; Drew McDowell, Executive Assistant; Katie McKeough, Press Assistant; Alex Miller, Video Production Aide and Press Assistant; Brandon Mooney, Senior Policy Advisor, Energy; James Paluskiewicz, Professional Staff, Health; Mark Ratner, Policy Coordinator; Annelise Rickert, Counsel, Energy; Dan Schneider, Press Secretary; Kristen

Shatynski, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; Danielle Steele, Policy Coordinator, Health; John Stone, Senior Counsel, Health; Hamlin Wade, Special Advisor, External Affairs; Jeff Carroll, Minority Staff Director; Elizabeth Ertel, Minority Office Manager; Waverly Gordon, Minority Health Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Rick Kessler, Minority Senior Advisor and Staff Director, Energy and Environment; Jessica Martinez, Minority Outreach and Member Services Coordinator; Dan Miller, Minority Staff Assistant; Jon Monger, Minority Counsel; Alexander Ratner, Minority Policy Analyst; Tim Robinson, Minority Chief Counsel; Samantha Satchell, Minority Policy Analyst; Matt Schumacher, Minority Press Assistant; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Health Policy Advisor; Tuley Wright, Minority Energy and Environment Policy Advisor; and C.J. Young, Minority Press Secretary.

The Chairman. Good morning, everyone. If the committee would come to order we will begin our markup, and I yield myself such time as I may consume for opening statement.

Good morning, buckle up. We have 15 bills to consider today in the Energy and Commerce Committee. Among these are important health priorities like the Food and Drug Administration Reauthorization Act of 2017. We have 11 bills aimed at advancing our nation's energy infrastructure and improving energy efficiency.

The FDARA is critically important legislation for patients, drug and device manufacturers, and the millions of Americans who work in the healthcare sector. FDARA would reauthorize the agency's critically important drug and medical device user fee programs, making improvements to each of them based on lengthy deliberations involving the FDA, industry, patient groups, and other stakeholders.

Under the leadership of Dr. Burgess, the Health Subcommittee made several improvements to the underlying bill from how the FDA inspects device establishments to enhanced generic drug competition through new incentives. FDARA will make a number of targeted, meaningful, and bipartisan steps to improve the process for generic drug approval and close loopholes that allow companies to increase prices for off-patent drugs when there is no competition.

As I have said before in this room, if we do not have this

bill to the President's desk in July, not only will thousands of FDA employees be seeking new employment, but desperately needed treatments and cures will not reach patients. We cannot and we will not stand for that.

We are also considering three important public health bills. These bills will advance research, surveillance, prevention, and treatment relating to sickle cell disease, improve the CDC's congenital heart disease surveillance system, and update the DEA registration process for certain mobile medical practitioners operating outside their principal place of practice.

These important public health bills aren't the only reason we are here today. When Congress can take steps that allow for more domestic energy output, lower costs for ratepayers, reduced emissions, and more jobs, it should not hesitate to do so. This is especially true if it can be done at little or no cost to taxpayers. That is what we hope to accomplish with today's slate of bipartisan energy bills.

From measures that facilitate increased generation of clean and affordable hydropower to wider use of energy savings performance contracts that cut down on energy use in federal buildings to programs for reducing energy costs in public schools, these bills will all lead us toward the common goal of smarter energy use. These and other projects are also job creators, which is why also have provisions to update and improve federal job training programs for the energy and manufacturing sectors.

So I look forward to advancing all of these important bills and would like to thank the entire committee for its dedication in identifying important ways to help patients and enact solutions that put consumers first. I now recognize my friend from New Jersey Mr. Pallone for 3 minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman. Today the committee will consider 15 bills including the FDA Reauthorization Act of 2017. We will begin by marking up 11 bipartisan energy bills, most of which were passed overwhelmingly by the House last Congress. I support these bills and commend Chairman Walden and Upton for working with us on them.

I am pleased that the majority agreed to mark up Ranking Member Rush's bill to promote a 21st century energy and manufacturing workforce. I am also encouraged that we will consider Representative Peters' Hydropower Permit Extension (HYPE) Act, and nine noncontroversial energy bills.

I also support the other health bills, H.R. 1222, the Congenital Heart Futures Reauthorization Act, and H.R. 2410, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act. Both of these bills are bipartisan measures that aim to improve outcomes for people with serious health conditions. And I also want to voice my support for H.R. 1492 which would allow registered physicians to transport controlled substances from practice location to another.

Finally, we are considering critical legislation to

reauthorize FDA's medical product user fee programs. The reauthorization of FDA user fee programs have always been approved in a strong bipartisan fashion. I am hopeful that tradition will continue again this year so the medical product review process will continue uninterrupted. This is a critical process that ensures patients and families have access to the innovative medical treatments they need to live longer and more productive lives.

Mr. Chairman, I wanted to mention once again, I mentioned it in the subcommittee, I ask that you hold a hearing on the rising costs of prescription drugs. I made this same request when this legislation was marked up in subcommittee because drug prices continue to rise at an alarming rate and the American people are rightfully demanding action.

A recent national poll found that 6 in 10 Americans believe lowering the cost of prescription drugs should be a top priority for the President and Congress and I certainly agree. Ensuring patient access to affordable and innovative prescription drugs should be a top priority of this committee and therefore I once again request that this committee hold hearings to examine rising drug costs.

And I would also point out that this is a bipartisan issue. You will remember during the presidential campaign both Hillary Clinton and President Trump mentioned prescription drug pricing and the need for Congress in Washington to get behind legislation

initiatives that would reduce drug prices and the President continues to talk about ways to accomplish that. So I think it is about time for this committee to have a hearing.

I look forward to our discussion on the bills before us and hope that each can advance with strong bipartisan support. I yield back.

The Chairman. The gentleman yields back. The chair now recognizes the gentleman from Michigan, Mr. Upton.

Mr. Upton. Thank you, Mr. Chairman. So yesterday I was proud to visit the Pfizer manufacturing facility in my district in Kalamazoo and Portage, Michigan, their largest one, by the way, in the world, and during our visit we talked about the facility's economic impact.

Two billion dollars spent in local economic activity, $6 billion in sales for Pfizer at that facility, thousands of jobs obviously in Southwest Michigan after a recent expansion.

We also discussed the vital need to pass the FDA User Fee Reauthorization bill on time so that they can capitalize on the work as we did in passing 21st Century Cures and continue to bring lifesaving drugs to market. We know that we heard from hearings that as many as 70 percent of those regulators at the FDA would be riffed without soon passage of this important legislation.

In addition to that Pfizer facility we have lots of other jobs impacted by this legislation. I want to thank the chairman for scheduling the markup on the 11 energy bills and I yield back

the balance of my time.

The Chairman. The gentleman yields back the balance of his time.

The chair recognizes the gentleman from Illinois, Mr. Rush.

Mr. Rush. I want to thank you, Mr. Chairman. Mr. Chairman, I am pleased to be here today to advance these 15 bills to the floor for their consideration. Most of these nine controversial bills have received consideration before the House and passed with overwhelming numbers.

Mr. Chairman, I am delighted to see the inclusion of my bill, H.R. 338, a bill to promote a 21st century energy and manufacturing workforce included at this markup, and I am grateful to my colleagues on both sides of the aisle who have worked with me to advance this bill.

I am so pleased by the committee's desire to promote renewable energy sources, namely hydropower. I am encouraged by the bipartisan manner in which we have approached this and I look forward to working together to continue to increase the availability of green energy in a manner that does not sacrifice our overall environmental protection concern.

Mr. Chairman, as to the healthcare bills before us I want to speak on an issue that is very personal to me. I am grateful to all of you and the staff for your work on advancing H.R. 1222, the Congenital Heart Futures Reauthorization Act of 2017. As you know, Mr. Chairman, cardiovascular disease disproportionately

affects African American women and at least 50,000 deaths annually is the leading cause of their death. This is also a disease that affects 49 percent of African American women 20 years and older.

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

The Chairman. The gentleman yields back the balance of his time.

The chair recognizes the gentlelady from Tennessee, Mrs. Blackburn, for 1 minute.

Mrs. Blackburn. Thank you, Mr. Chairman. I have been so pleased to work with Mr. Kennedy on the Over-the-Counter Hearing Aid Act and am so pleased that it is included. This is a provision that has bipartisan support. It came out of the Health Subcommittee on May 18th.

We have continued to work with all the concerned stakeholders on this legislation and know that this is a provision that is going to bring relief to millions of Americans who suffer from untreated hearing loss while assuring that the FDA will retain their authority to ensure the safety and efficacy of these devices. And I appreciate the support and help, yield back.

The Chairman. The gentlelady yields back. Are there other members on the minority side seeking recognition?

Ms. Eshoo? Ms. Eshoo, no. Mr. Green recognized for 1 minute.

Mr. Green. Thank you, Mr. Chairman. We are considering a number of bills today related to energy and health care, but I

want to focus on my opening statement on the FDA user fee agreements.

For many months now we have worked on a bipartisan basis in our subcommittee to examine and prepare the four user fee agreements for reauthorization. They must be reauthorized in a timely manner to avoid a meltdown of the medical product development pipeline. Failure to do so would lead to a huge number of layoffs, investigational clinical trials grinding to a halt, and as one person put it, a calamity of Titanic proportions.

There have been great collaboration and strong working relationships across party lines through the goals letter to the subcommittee approval last month. This must-pass nature of this package is important. We all understand and should resist temptation to add last-minute, poison pill amendments that would threaten the timely authorization of these user fees. These user fees need to be reauthorized and we have done in this committee for 20 years.

I hope to continue the bipartisan cooperation and look forward to today's markup in this critically important package and I thank the chair and yield back.

The Chairman. I thank the gentleman and now recognize the gentleman from Ohio, Mr. Latta, for 1 minute.

Mr. Latta. Well, thank you very much, Mr. Chairman. I applaud the committee's effort to bring forth numerous bipartisan

pieces of legislation today. I am pleased to support the bills before us that will promote sound energy policies, support public health initiatives, and reauthorize essential FDA user fee programs. Furthermore, I am glad to be leading an effort to modernize another important FDA process, the over-the-counter monograph system.

For the past year, I have been collaborating with our colleagues Mr. Green, Ms. DeGette, and Mr. Guthrie to deliver much needed reform as to how the FDA reviews the over-the-counter drug medicines. Our bill will update an inadequate system that has been in place for over 40 years to allow for advancements in science that benefit consumers.

I look forward to continuing our work with this common sense proposal that will facilitate innovation and growth in the over-the-counter marketplace and increase consumer confidence and choice. And with that Mr. Chairman, I yield back. Thank you.

The Chairman. The gentleman yields back.

Are there other members on the Democratic side seeking recognition? Ms. Schakowsky, you are recognized for 1 minute.

Ms. Schakowsky. Thank you. There are so many provisions in the user fee agreement that I support, but we are once again passing up the opportunity to do something about reducing the cost of prescription drugs, something the President has been repeatedly talking about throughout the campaign and since.

I do want to thank the Republicans and my Democratic

colleagues for supporting my bipartisan amendment that would improve postmarket safety for medical devices through a voluntary program, but I also want to say as the Chairman said, we need to pass this bill or pink slips will appear at the FDA.

But I think the addition of an amendment that has not really been discussed that could compromise safety, the off-label communications amendment, should be dropped so that we can all agree on passing this bill and making sure we protect the FDA. I yield back.

The Chairman. The gentlelady yields back.

The chair now recognizes the whip of the House, Mr. Scalise, for 1 minute.

Mr. Scalise. Thank you, Mr. Chairman. I want to thank you for holding this markup today and let me start with the energy bills that we have under consideration. As President Trump and Secretary Zinke discuss energy dominance, I am proud that the Energy and Commerce Committee is doing its part to assist in that effort.

I have always been a strong supporter of an all-of-the-above energy strategy that includes all forms of generating power, so today I am glad that the committee is considering bills that will make it easier to build and extend the life of several hydroelectric projects including one in my home state of Louisiana. Specifically, the J. Bennett Johnston Waterway Hydroelectric Extension Act of 2017 will extend the license period

for three hydroelectric projects on the Red River, giving them additional time to secure a power purchase agreement and begin construction.

These projects will provide hundreds of jobs for Louisiana families and I want to commend my colleague, Congressman Mike Johnson, for introducing this important bill. These hydro projects not only support high paying jobs, but also ensure that electric rates remain competitive which is critical to our economy as it emerges from sluggish growth over the last 8 years. And then of course the FDA reauthorization bill, very important for families to get access to affordable medicine and ensure that families can continue to benefit from an innovative medical sector.

Thanks again, Mr. Chairman, for the hearing. I yield back the balance of my time.

The Chairman. I thank the gentleman from Louisiana.

And now other members seeking recognition, Mr. Butterfield?

Mr. Butterfield. Mr. Chairman, I don't have a protracted statement. I just want to thank you for your leadership and your willingness to work with Mr. Pallone in working through many of these amendments. It speaks volumes about your leadership.

And your staff is to be commended because they work with my staff and other staffs to make markups like this very streamlined, and so I simply wanted to say that publicly. Thank you very much. I yield back.

The Chairman. I appreciate that. Thank you very much.

Are there other members on the Republican side seeking recognition? Are there other members -- oh, Mr. Bucshon. Dr. Bucshon, recognized for 1 minute.

Mr. Bucshon. Thank you, Mr. Chairman. The FDA Reauthorization Act we will consider today represents an agreement between industry and the FDA with input from the committee to provide FDA the resources it needs to help move innovative drugs and devices to market in a timely and transparent fashion. Specifically, the medical device title reflects language I introduced with Representatives Brooks, Peters, and Butterfield, which sets forth a risk-based approach to medical device establishment inspections.

Our language allows FDA to focus its resources where they are needed most and provides device manufacturers the transparency and certainty they need to bring innovative products to patients in an efficient manner. I urge my colleagues to support the legislation. I look forward to moving it through the committee and to the House floor, and I yield back the balance of my time.

The Chairman. The gentleman yields back the balance of his time.

Are there other members on the Democratic side? Ms. Castor of Florida is recognized for 1 minute.

Ms. Castor. Thank you, Mr. Chairman. And I would like to

thank all of my colleagues for working together on a good package of bipartisan bills, but I do think we are missing an opportunity to stand up for families all across this country and to address the high cost of prescription drugs.

And I will associate myself with Congresswoman Schakowsky and her remarks. This is June, the Congress has been in for half of a year now. There has been no hearing on one of the most pressing problems in front of American families and health professionals, the skyrocketing cost of prescription drugs. I think that is a dereliction of duty. We have a responsibility in this committee to stand up for the families that we represent.

And I know you are hearing from them just like I am back home in Florida that this is a real drag on their ability to provide for their families and they just can't believe that the Congress would not at least be having a hearing. I noticed that they are having hearings over on the Senate side and we shouldn't abdicate our responsibility. We should at least have the FDA, the new FDA administrator, here, to discuss joint policy goals on reducing the cost of prescription drugs.

Thank you and I yield back.

The Chairman. The gentlelady's time has expired.

The chair now recognizes, I believe we are down to Mr. Carter on the Republican side.

Mr. Carter. Thank you, Mr. Chairman. Mr. Chairman, I want to thank you for the opportunity to provide opening remarks and

for the committee's hard work on this issue. The FDA Reauthorization Act is a move in the right direction as we seek sensible reforms to the way we handle drugs and devices in our healthcare system.

By streamlining the approval process, overhauling the information sharing network, and setting benchmarks for reviews, we can provide greater autonomy and opportunity to the consumer and to the patient. We have made some progress in the approval of rare disease drugs, helping millions who suffer from diseases that often have no treatment. With this bill we can see that begin to change. Additionally, we will be able to see more generics entering the market, increasing competition and driving down costs for consumers.

I would also like to thank the committee for their continuing work on compounding medications and I look forward to constructive cooperation that will give millions of Americans the opportunity to pursue a different medical approach.

I want to applaud the chairman, the committee, and all of my colleagues for their hard work on this legislation and I hope that we can work collaboratively on this and other issues that will give Americans more choices at lower cost.

Thank you and I yield back.

The Chairman. Are there members on the Democratic side seeking -- Mr. Welch is recognized for 1 minute.

Mr. Welch. Thank you, Mr. Chairman. This is a very

important bill and I am looking forward to it being passed, but I take up what Kathy Castor just said. The price of prescription drugs is killing us. Pharma does good things. It creates pain-relieving and life-extending products. That is good for us, but the cost is crushing us. We have an example of EpiPen where if people buy it in Canada it is like $250; in the U.S. it is 600.

And the pain to families, I got a letter from a Vermonter who said, Mr. Welch, I have a choice between paying for something I cannot afford or risking a loss -- of her son -- that I could never endure.

We pay the highest prices in the world. Now why don't we have consideration for that mom struggling to protect her son when there is an ability to do that? Drug prices and profits are like the highest they have ever been. The top ten executives were paid $347 million.

Doesn't that mother, doesn't a truck driver, doesn't a farmer have the right to the consideration of this committee? This is a big problem in America. 330 million people live here. There is 54 in this room who today have an opportunity to provide some help to the people we represent. Mr. Chairman, I hope we do.

The Chairman. The gentleman's time has expired.

Are there other members on the Republican side seeking recognition? Seeing none, are there others on the Democratic side seeking recognition? Seeing none, then we are prepared to move forward.

The chair asks unanimous consent that the committee adopt and favorably report to the House of Representatives H.R. 338.

[The Bill H.R. 338 follows:]

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The Chairman. This is a bill to promote a 21st Century Energy and Manufacturing Workforce. For what purpose does the gentleman from Illinois seek recognition?

Mr. Rush. Move to strike the last word, Mr. Chairman.

The Chairman. The gentleman is recognized for 5 minutes.

Mr. Rush. I want to thank you, Mr. Chairman. This 21st Century Workforce bill represents hope and opportunity for many of our fellow citizens who feel that they have been locked out of the American dream. Specifically, the bill would direct the secretary of energy to prioritize the training of underrepresented groups including minorities, women, and veterans as well as displaced and unemployed energy and manufacturing workers in order to increase the number of skilled candidates trained to work in these related fields.

This bill would strengthen and more fully engage Department of Energy programs and national laboratories in order to carry out the Department's workforce development initiative. At the same time, Mr. Chairman, this legislation will help to develop a skilled labor force trained to work in a wide array of sectors including renewables, energy efficiency, oil and gas, coal, nuclear, utility, pipeline, alternative fuels, as well as energy-intensive and advanced manufacturing industries.

We know, Mr. Chairman, that the energy and manufacturing industries are two of the most critical and fastest-growing sectors. The potential of these two industries can help bolster

the American economy and the middle class and the working class. For these reasons, Mr. Chairman, it is important that we equip our citizens with the skills needed to meet this growing demand so that we can tap into these tremendous opportunities. Simply put, Mr. Chairman, this bill will help accomplish that goal and I yield back.

Mr. Green. Will the gentleman yield?

Mr. Rush. I yield to my friend from Texas.

Mr. Green. Instead of asking for my own 5 minutes, I thank my colleague. Congressman Rush, thank you for introducing this bill and I am proud to be a cosponsor of it. I represent a very energy-intensive district with downstream and upstream companies, and to this day even though the cost of oil is hurting in the oil patch, the downstream, the chemical industry, the refinery industry, the people who service those, it is so important to have skilled employees.

And there are programs but this would help us put these programs together and working around community college to make sure that they are training for a skill that is there and not one just to be training. And that is what is important and that is why last Congress -- thank you, Congressman Rush, for doing this. Hopefully we will get this bill passed in this Congress, and thank you for yielding time to me. I yield back.

Ms. Castor. Well, I also want to thank Congressman Rush for his leadership on this bill, H.R. 338. It is very important. You

have been at it for a number of years, Congressman Rush.

But I wanted to share with you, I recently paid a visit and had a briefing at one of our Department of Energy national laboratories where the director said this is a very important issue. They are trying to be proactive about it, but they need additional tools to increase the diversity and outreach to the workforce.

I also continue to hear from businesses and manufacturers all across the state of Florida that are in dire need of skilled talent. And unless we really put our heads together and are proactive in doing that broad-based outreach that your bill provides, we aren't going to have the skilled workforce that we need to compete globally.

So I wanted to thank you again for your outstanding leadership on this issue and I yield back.

The Chairman. Are there other members seeking recognition on this bill? I recognize the gentleman from New Jersey, Mr. Pallone.

Mr. Pallone. Thank you, Mr. Chairman. I move to strike the last word. I am pleased that we are marking up Ranking Member Rush's bill to promote a 21st Century Energy and Manufacturing Workforce. This widely supported important bill establishes a DOE program to help deploy minorities, women, veterans, and displaced workers into the energy sector, and we have to be investing in workforce development and job training.

I did want to comment though, in general, in terms of the committee and energy policy today if I could, Mr. Chairman. I was very disappointed as you can imagine with President Trump's decision last week to pull our nation out of the landmark Paris Climate Accord and I think that that puts even greater onus on Congress to address our nation's carbon pollution.

In our new post-Paris landscape I hate to mention the word but it is true, because of the President this committee needs to be doing more to address climate change now that the Trump administration has abdicated its responsibility. We can't just recycle energy proposals from last Congress which were developed with the Paris framework in place, we need an energy policy that embraces the deployment of newer, cleaner, and cheaper technology that will expand our energy choices while reducing both consumers' bills and pollution.

While the energy bills before us today are worthwhile, our committee should be thinking bigger and doing more to invest in energy infrastructure and our clean energy future. Much of our energy infrastructure is aging or outdated and doesn't serve our current and future energy needs. This committee should be focusing on modernizing our infrastructure by reducing vulnerabilities to climate change and attacks from those seeking to do us harm, and our efforts should also facilitate the deployment of smarter electric grids that support more distributed and renewable energy generation.

There is a lot of talk about infrastructure around the nation's capital. President Trump talked about a trillion dollar infrastructure bill during his campaign. And of course in the last week, I don't know if it was leaked or something was put out from the White House suggesting what their infrastructure bill might be. That was a disappointment to me because it seemed to elect to depend primarily on funding from state and local sources rather than federal dollars.

I think if we are going to have a federal infrastructure program it needs to be primarily with federal dollars, certainly not with the states and the towns who can't afford it. I mean I know in New Jersey, you know, my mayors and state legislators, we actually had our primary yesterday, many of them were sort of ridiculing this proposal by the President because they said, you know, we don't have the money to do the infrastructure, I thought that is what the federal government was going to do.

So we have actually, as Democrats we have introduced a bill called the LIFT America Act which includes a robust energy infrastructure title that would modernize our grid, fund efficiency upgrades, and reduce carbon pollution while creating jobs. Every Democrat on the committee has cosponsored this bill.

If the majority wants to promote new energy infrastructure and further job creation as Chairman Walden stated in announcing this markup, we stand ready to discuss our proposal or others. Gutting public health and environmental standards, cutting taxes

and turning assets over to big Wall Street banks will not foster the infrastructure investment our country really needs. We need sustained federal investment that will create jobs, modernize our energy economy, and reduce our nation's carbon pollution.

I yield back, Mr. Chairman.

The Chairman. I thank the gentleman, if he would yield just a second to me perhaps.

Mr. Pallone. Oh yes, certainly I will yield to you.

The Chairman. I appreciate the gentleman's comments. And as he knows, our committees and our subcommittees have been doing a lot of work together on some other legislation that will be coming in the next few weeks that will address a lot of the issues you have talked about. We will have our differences obviously on certain things and funding levels, but we concur. And newer, cleaner energy sources that benefit consumers, reduce pollution, increase conservation, and maximize the ability of those who need to update their systems in a more timely way through some permit revisions and things of that nature.

So I actually look forward to working with you and colleagues on both sides of the aisle. I think there is a lot of common ground here. Admittedly, there will be some differences as we all know, but I think when it comes to Brownfields legislation, when it comes to approving Safe Drinking Water Act, some of these laws have not been updated in 10 years, 15 years, 20 years, yeah. And so we have taken it seriously to look at these laws and say okay, how

would we update them for the 21st century and we are going to continue that throughout our jurisdiction not only on energy and telecommunications, but elsewhere.

Mr. Pallone. If I could reclaim my time.

The Chairman. Yeah, sure.

Mr. Pallone. I guess I should also mention and, you know, you and I and the ranking members on the Energy Subcommittee have had some discussions with the senators, Senator Murkowski, Senator Cantwell have approached us. We did try as Mr. Upton knows at the end of the last session to move to some extent on the energy bill that passed the House and that passed the Senate. I am not saying that we have to, you know, reshuffle that but obviously there is interest in the Senate as well on moving some, you know, on energy bills. So I did want to mention that as well.

The Chairman. Yes. I think that is very good. The gentleman yields back the balance of his time. Are there other members seeking recognition or can we move forward on this bill? Yes, Ms. Clarke of New York.

Ms. Clarke. Thank you, Mr. Chairman. I move to strike the last word. I wanted to thank the gentleman from Illinois, Mr. Rush, for his steadfast commitment to really making sure that we produce a 21st century workforce. This bill, H.R. 388, directs the secretary of energy to prioritize education and training of underrepresented groups, communities of color, women, veterans, and displaced unemployed energy and manufacturing workers, in

order to increase the number of skilled candidates trained to work in these related fields.

And I know that this is a passion that we both share and so I wanted to just take the moment to say job well done, Mr. Rush, and I look forward to supporting you and supporting the Department of Energy as they formulate ways to reach into these communities to make sure that we bolster the numbers of individuals who will be taking these jobs in the 21st century. Congratulations once again, Mr. Rush, and I yield back.

The Chairman. The gentlelady yields back the balance of her time. The chair asks unanimous consent that the committee adopt a favorable report to the House of Representatives, H.R. 338, a bill to Promote 21st Century Energy and Manufacturing Workforce. Without objection, so ordered.

The chair asks unanimous consent that the committee adopt and favorably report to the House of Representatives H.R. 627, the Streamlining Energy Efficiency for Schools Act of 2017.

[The Bill H.R. 627 follows:]

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The Chairman. Without objection, so ordered.

The chair asks unanimous consent that the committee adopt and favorably report to the House of Representatives H.R. 723, the Energy Savings Through Public-Private Partnership Act of 2017, with an amendment filed by Mr. Upton.

[The Bill H.R. 723 follows:]

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

The Chairman. Without objection, so --

It is a Kinzinger bill. It is an amendment by Mr. Upton. Without objection, so --

Mr. Rush. Mr. --

The Chairman. Oh, I am sorry. Does someone seek recognition?

Mr. Rush. Yeah, I move to strike the last word.

The Chairman. The gentleman is recognized for 5 minutes.

Mr. Rush. Mr. Chairman, I move to support this bill, H.R. 723, the Energy Savings Through Public-Private Partnership Act of 2017. This legislation offered by my friend and colleague from Illinois, Mr. Kinzinger, and my friend from Vermont, Mr. Welch, lists several useful clarifying changes to the implementation of energy savings performance contracts which allow the federal government to contract for energy saving and water saving improvements in federal buildings that are paid for with the resulting energy and water savings over the life of the contract.

Mr. Upton, Mr. Chairman, would be offering a purely technical amendment that adds a missing semicolon back into the bill. We have no problem with semicolons or Mr. Upton's amendment, not any.

The Chairman. Whew.

Mr. Rush. In any case, Mr. Chairman, this is good, common sense legislation that both sides of the aisle support it as part of last year's energy bill. It is still worthy of our support and I would urge that it is favorably reported. I yield back.

The Chairman. And the gentleman yields back the balance of his time. We appreciate his comments.

Mr. Rush. We have semicolons.

The Chairman. The chair asks unanimous consent that the committee adopt a favorable report to the House of Representatives, H.R. 723, the Energy Savings Through Public-Partnership Act of 2017 with an amendment filed by Mr. Upton. Without objection, so ordered.

The chair asks unanimous consent that the committee adopt a favorable report to the House of Representatives, H.R. 1109. This is a bill to Amend Section 203 of the Federal Power Act.

[The Bill H.R. 1109 follows:]

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

The Chairman. Without objection -- the gentleman from New Jersey seeks recognition. Oh, my apologies, I missed that. Do you want to speak on this one in support of the last one?

Mr. Welch. Well, I was going to say some good things about my Republican colleagues.

The Chairman. Oh, please. We all yield you 22 minutes. I apologize. I recognize the gentleman from Vermont.

Mr. Welch. I was waiting for Mr. Kinzinger but maybe he is not here. I just wanted to say that it has been a longstanding effort on the part of Republicans and Democrats to take advantage of energy efficiency. It is a place where there has been significant common ground in real common effort.

Adam Kinzinger and I have worked on this. He has done a great job in the previous Congress when Cory Gardner was a colleague on this committee. He is now in the Senate. He is cosponsoring this bill with Senator Coons. And what is tremendous about this is that we all agree that less is more when it comes to using energy and whatever the fuel source, if you are using less and you are saving money that is a good thing.

And it is also a good thing because when you are implementing energy efficiency projects, as Mr. McKinley and I know, you are putting local folks to work. And in this legislation what we are trying to do is clear away the obstacles to the federal government, which is a huge energy consumer, from being able to retrofit its buildings and the public-private partnership here allows for

energy saving performance contracts and utility saving performance contracts to make a bid.

They do an audit on the building and they show us where they can save money, and then here is the great thing, they put the at-risk money up front to implement those changes and get paid on the back end as energy consumption declines and we receive, we the taxpayers receive the benefit of that retrofit. So it is just a tremendous practical opportunity for us to save energy, lower our carbon footprint, put people to work, and not put taxpayer money at risk.

So I want to thank my colleagues on the Republican side for their leadership on this and I want to thank Mr. Rush and my colleagues on the Democratic side. But we have got to make it possible for the ESPCs and the utility performance contractors to get this done and not have obstacles that are legislative and bureaucratic. So I thank you, Mr. Chairman, for having this be part of the legislation.

The Chairman. Please continue on.

Mr. Welch. You have had enough for 1 day.

The Chairman. Oh yeah, I know. Trust me. Yeah, we call it the PPPWWW, Public-Private Partnership Win-Win-Win. So I think this is really solid legislation. Are there others seeking recognition on this?

Mr. Pallone. Are we on Walberg now or --

The Chairman. No, we are on the 1109.

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

The Chairman. The gentleman from New Jersey is recognized for 5 minutes.

Mr. Pallone. Thank you, Mr. Chairman. H.R. 1109 sponsored by Representatives Walberg and Dingell would add a $10 million threshold to trigger FERC review of a merger or consolidation since under current law no such threshold exists. This is a significant change to current laws established by the Energy Policy Act of 2005, wherein Congress essentially did away with the Public Utilities Holding Company Act, or PUHCA, as it had existed for 70 years, in order to reduce the burden on industry. This also fundamentally altered and strengthened Section 203 of the Power Act to protect against potential market abuses that might arise without the protections of PUHCA.

So I am pleased that the sponsors have retained language added by Energy Subcommittee Ranking Member Rush last Congress to ensure that FERC will be notified if significant transactions below the new threshold so that it can take action against efforts to break up serial transactions designed to specifically evade the review trigger. This is balanced legislation that deserves to be favorably reported.

Did you want me to yield to you? I yield to the gentlewoman from Michigan.

Mrs. Dingell. Thank you, Mr. Pallone. I move to strike the

last word. Mr. Chairman, 1109 is a common sense solution that saves consumers money while also helping to make our government run more efficiently. I want to thank the committee for taking up the bill and my colleague Representative Walberg for working with me on this important issue. It is an example of how we need to work together more.

Just this week, a company in Michigan had to file a 71-page document with FERC for a Section 203 authorization for the purchase of a high voltage transmission facilities. The net book value for those assets was $164.23, 71 pages for a $164 transaction. Because there is no de minimis threshold for the acquisition of transmission facilities by merger, consolidation, or other means, companies have been obligated to submit filings on transactions as small as this one. It is a waste of resources for companies and for FERC.

H.R. 1109 will put a stop to this. It would reduce needless regulation and consumer costs by increasing the threshold for FERC approval from 50,000 to 10 million. Any transaction between a dollar and 10 million would also require notification after such transactions are completed. This still allows FERC to monitor large transactions as they have done in the past. It is a win for consumers, companies, and FERC. I thank the chairman for including this today in the markup. I urge my colleagues to support it and yield back the remaining of my time.

Mr. Pallone. And I yield back, Mr. Chairman.

The Chairman. The gentleman yields back. The chair recognizes the gentleman from Michigan, Mr. Walberg, for 5 minutes. Is that right?

Mr. Walberg. Thank you, Mr. Chairman, and I appreciate the work of committee staff on both sides of the aisle for their time and work on this issue. And I just wanted to make a brief comment so it is not just my good friends and colleagues on the other side of the aisle that are applauding the good work that is being done, but it comes from this side as well.

I would like to thank my colleagues, especially my good friend and colleague from Michigan, Representative Dingell, for cosponsoring this with me and making this bipartisan legislation. H.R. 1109 will help reduce the unnecessary paperwork burdens and bring down energy prices for American families and that is an important thing today. This bipartisan solution unties FERC's hands and allows the Commission to ensure American ratepayers are getting the most affordable and reliable electricity possible. And that is, I think, what we are all about, Mr. Chairman, and with that I yield back.

The Chairman. The gentleman yields back. The chair asks unanimous consent the committee adopt favorable report to the House of Representatives H.R. 1109, Bill to Amend Section 203 of the Federal Power Act. Without objection, so ordered.

The chair asks unanimous consent that the committee adopt in favorable report to the House of Representatives H.R. 446.

This is a bill to extend the deadline for commencement of construction of hydroelectric project Flannagan, Virginia.

[The Bill H.R. 446 follows:]

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

The Chairman. Without objection, so ordered.

The chair asks unanimous consent that the committee adopt favorable report to the House of Representatives H.R. 447. This is a bill to extend the deadline for commencement of construction of a hydroelectric project, Gathright, Virginia.

[The Bill H.R. 447 follows:]

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

The Chairman. Without objection, so ordered.

The chair asks unanimous consent that the committee adopt favorable report to the House of Representatives H.R. 951, a bill to extend the deadline for commencement of construction for hydroelectric project W. Kerr Scott, North Carolina.

[The Bill H.R. 951 follows:]

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

The Chairman. Without objection, so ordered.

The chair asks unanimous consent the committee adopt favorable report to the House of Representatives H.R. 2122, a bill to reinstate and extend the deadline for commencement of construction of a hydroelectric project involving Jennings Randolph Dam, West Virginia.

[The Bill H.R. 2122 follows:]

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

The Chairman. Without objection, so ordered.

The chair asks unanimous consent the committee adopt favorable report to the House of Representatives H.R. 2274, the Hydropower Permit Extension Act.

[The Bill H.R. 2274 follows:]

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

Mr. Peters. Mr. Chairman?

The Chairman. The gentleman from California is recognized to strike the last word.

Mr. Peters. Strike the last word, thank you. Thank you, Mr. Chairman. Hydropower is one of the few truly carbon-free energy sources that provides a steady baseload of electricity. Producing more electricity from hydro is essential to meeting our clean energy goals and reducing harmful emissions that pollute our air and water.

My bill, the Hydropower Permit Extension or HYPE Act would cut red tape in the construction permitting process for hydropower projects and incentivize greater investment in carbon-free hydropower. This bill gives already approved hydropower projects an extra year on their initial permit to begin construction and also grants FERC the authority to give hydropower projects a 4-year extension if delays prevent them from beginning construction during the initial permit. Right now it requires an act of Congress to extend construction permits for hydropower projects even though the projects have already undergone a rigorous approval process.

So today, the committee is considering six bills that involve extending the construction permit for specific hydropower projects. If HYPE were to become law we could spend less time on those kinds of issues here.

The ultimate solution to unlocking hydro is to streamline

the regulatory process so that projects can be approved more quickly while still meeting high environmental standards. But in the meantime, this bill will provide greater certainty and ensure that more of the hydropower projects that are approved actually get built.

So I would like to thank the chairman and ranking member for bringing forward this straightforward bill to the committee for a vote. I urge my colleagues to support the bill and yield back the balance of my time.

The Chairman. The chair asks unanimous consent the committee adopt favorable report to the House of Representatives H.R. 2274, the HYPE Act, the Hydropower Permit Extension Act. Without objection, so ordered.

The chair asks unanimous consent that the committee adopt favorable report to the House of Representatives H.R. 2292. This is a bill to extend a project of the Federal Energy Regulatory Commission involving the Cannonsville Dam.

[The Bill H.R. 2292 follows:]

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

The Chairman. Without objection, so ordered.

And the chair asks unanimous consent the committee adopt favorable report to the House of Representatives H.R. 2457, the J. Bennett Johnston Waterway Hydropower Extension Act of 2017, with amendment filed by Mr. Upton.

[The Bill H.R. 2457 follows:]

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

The Chairman. The chair recognizes the gentleman from Illinois, Mr. Rush, to strike the last word.

Mr. Rush. I want to thank you, Mr. Chairman. I move to strike the last word. All right. Mr. Chairman, H.R. 2457, the J. Bennett Johnston Waterway Hydropower Extension Act of 2017 was introduced by my friend, Representative Mike Johnson, on May 16th, 2017. The bill would extend the time period in which the licensing is required to commence the construction of this project for up to three consecutive 2-year periods from the date of the expiration of the original extension. Additionally, Mr. Chairman, the legislation defers the obligation on the licensee to pay any annual charges required under FPA Section 10(e) until the project actually commences construction. Finally, Mr. Chairman, the legislation allows for the prospective reinstatement of the license should that license expire prior to the legislation's date of enactment.

Mr. Upton is offering an amendment making a technical change to the bill request by FERC. I have no objection to an amendment on the bill and urge that we favorably report the amendment and legislation and I yield back.

The Chairman. The gentleman yields back the balance of his time. Are there other members seeking recognition? Hearing none, the chair asks unanimous consent the committee adopt favorable report to the House of Representatives H.R. 2457, the J. Bennett Johnston Waterway Hydropower Extension Act of 2017 with

the amendment filed by Mr. Upton. Without objection, so ordered.

I thank the committee for their good work on these energy bills and now we will move on to some healthcare legislation that is exceptionally important.

The chair calls up H.R. 1222, as amended, by the Subcommittee on Health on May 18th, 2017, and asks the clerk to report.

[The Bill H.R. 1222 follows:]

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

The Clerk. H.R. 1222, to amend the Public Health Service Act to coordinate federal congenital heart disease research efforts and to improve public education and awareness of congenital heart disease and for other purposes.

The Chairman. Without objection, the first reading of the bill is dispensed with. The bill is open for amendment at any point. Are there any bipartisan amendments to the bill? Are there any amendments?

If not, I just want to thank the sponsor of this very important legislation for bringing this to our committee and the question now occurs on favorably reporting H.R. 1222, as amended, to the House.

All those in favor shall signify by saying aye.

Those opposed, nay.

The ayes appear to have it. The ayes have it. The bill is reported favorably.

The chair calls up H.R. 1492 and asks the clerk to report.

[The Bill H.R. 1492 follows:]

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

The Clerk. H.R. 1492, to amend the Controlled Substances Act to direct the attorney general to register practitioners to transport controlled substances to states in which the practitioner is not registered under the act for purpose of administering the substances under applicable state law at locations other than principal places of business or professional practice.

The Chairman. Without objection, the first reading of the bill is dispensed with. The bill will be open for amendment at any point. Are there bipartisan amendments to the bill? Are there amendments to the bill?

The question now occurs on -- the gentleman from Oregon is recognized to strike the last word.

Mr. Schrader. Just for a minute, Mr. Chairman. I just appreciate this. We will be voting for this bill. I just wanted to make sure that for the record it does not include veterinary medicine. We went to a lot of hard work the last couple of Congresses to make sure veterinarians in their ambulatory practices could carry their controlled substances wherever they needed to go to take care of the pain, suffering, and proper surgical and anesthetic use. So I just wanted to put this in the record this is for our physician colleagues in a very narrow circumstance. Thank you, Mr. Chairman.

The Chairman. I appreciate the gentleman's comments. It is important to get that in the record. The gentleman yields back

the balance of his time. The question now occurs on favorably reporting H.R. 1492, as amended, to the House.

All those in favor shall signify by saying aye.

All those opposed, no.

The ayes appear to have it. The ayes have it. The bill is favorably reported.

The chair now calls up H.R. 2410 and asks the clerk to report.

[The Bill H.R. 2410 follows:]

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

The Clerk. H.R. 2410, to amend the Public Health Service Act to reauthorize a sickle cell disease prevention and treatment demonstration program and to provide for sickle cell disease research, surveillance, prevention, and treatment.

The Chairman. Without objection, the first reading of the bill is dispensed with. The bill will be open for amendment at any point. Are there bipartisan amendments to the bill? Are there other amendments?

Seeing none, the question now occurs on favorably reporting H.R. -- the gentlelady from New York is recognized to strike the last word.

Ms. Clarke. Thank you very much, Mr. Chairman. I rise in support of H.R. 2410. Sickle cell disease is a serious blood disorder that causes acute pain, severe anemia, infections, and vascular blockages that can lead to organ damage and death. This is the most commonly inherited blood disorder in the United States, occurring most often in African Americans and Latinos. One in every 365 black children is born with sickle cell disease and it is estimated that 8 to 10 percent of black Americans have sickle cell traits like myself, many of whom never know that they are carriers, unfortunately.

Sickle cell disease suffers from a lack of critical funding directed towards the prevention, treatment, and cure of the disease. Fortunately, this bill creates a grant program that would support much needed research into this disease. One of the

allowable uses of the grant program is to fund public health initiatives. This enables not only more public education about the disease, but also can increase medical awareness of the disease. I was taught about my carrying of the trait while in public school in New York City where young school students were tested, so I think that this would go a long way in expanding that and reinvigorating that type of programming.

Those who have this disease experience acute painful flare-ups. Normally, our blood cells are round and easily flow through our veins, but during a flare-up a sickle cell patient's blood cells become distorted and take on a sickle-like shape as they push through the patient's veins. It is excruciatingly painful. Now imagine being denied painkillers by an emergency room doctor who writes you off as being a drug addict because of the negative cultural bias associated with minorities. Unfortunately, this is what many sickle cell patients face.

There have been scientifically valid studies that link pain management disparities to racial bias. This bias coupled with the opioid epidemic sweeping across America has made it even harder for sickle cell patients to receive prompt, appropriate treatment for their disease during a flare-up. It is my hope that some of the public health initiatives funded by this bill will help bring a new awareness of this disease to the medical community as well as increase the medical community's cultural competence. I ask my colleagues to join me in supporting this bill and I yield

back the balance of my time.

The Chairman. I thank the gentlelady for her comments and for her work.

Mr. Burgess. Would the gentlelady yield?

Ms. Clarke. Oh, yes. I would.

Mr. Burgess. Thank you. And Mr. Chairman, I didn't want to take --

The Chairman. No, that is fine.

Mr. Burgess. -- full time, but this is an important bill. And certainly Representative Davis has worked on this, dwelt on this for a number of years. When we had a hearing, I think it was in the last Congress not this Congress, and we heard testimony from the witness on the sickle cell disease issue that there had not been a new FDA-approved treatment for sickle cell disease in 40 years, that is why the treatment today looks like the treatment looked like in the 1970s when I was a resident at Parkland Hospital.

This is an important bill. It provides those support programs to find new solutions. I encourage members to be supportive and I yield back to the gentlelady.

Mr. Rush. Mr. Chairman.

The Chairman. The gentlelady controls the time. Do you want to yield to Mr. Rush or do you want your own time?

Mr. Rush. I want to strike the last word.

The Chairman. Pardon me?

Mr. Rush. I want to strike the last word.

The Chairman. Okay. The gentlelady yields back and I will recognize -- are there any members on the Republican side seeking recognition? If not, we go to the minority side. Mr. Rush is recognized for 5 minutes.

Mr. Rush. Mr. Chairman, I just want to speak on behalf of this bill. Some 50 years ago, Mr. Chairman, I was a member of an organization called the Black Panther Party. A lot of people have a lot of distorted opinions of the Black Panther Party. One of the initiatives that we took on as a party, as an organization, was sickle cell anemia. Sickle cell anemia was not a well-known disease, was not recognized by most in the medical profession because it really just predominately affected African Americans.

So as an organization, as a youngster -- I was 22, 23 years old -- a member of a pretty significant organization in my sight, we took on the challenge of actually testing for sickle cell anemia. We were going to churches, going to community organizations, take a prick of blood and take it back to our health centers and to the labs that we had access to -- University of Chicago, Mount Sinai Hospital, various others around the country -- and were able to actually inform sickle cell anemia patients or those who had the disease that they actually had the disease. This was some young people taking on this challenge.

And here we are, Mr. Chairman, some 50 years later and we have not advanced too much along the way of diagnosis or treatment

of sickle cell anemia. So I just take my hat off, Mr. Chairman, to my friend Dr. Burgess, to my friend and colleague and close associate Danny K. Davis of Illinois, and I am just proud of this moment. This is about 50 years in the making for me and I really honor this committee for this bill and I really hope that this bill sails out of this full committee. Thank you and I yield back the balance of my time.

The Chairman. I thank the gentleman for his words and for his passion and for his caring and I recognize the gentleman from North Carolina Mr. Butterfield.

Mr. Butterfield. Thank you, Mr. Chairman. I move to strike the last word. Chairman Walden, let me thank you again for your leadership and your willingness to work out this legislation and get it marked up without any controversy.

Thank you, Congressman Rush, for your very passionate words a moment ago. I know that you have been advocating for sickle cell anemia research for every year since I have been in Congress.

And to Dr. Burgess and to Ms. Clarke and to Mr. Davis who is not here today but certainly he has been a champion of this issue, thank you one and all.

Mr. Chairman, I am going to ask permission to include a letter in the record in support of H.R. 2410 from the Sickle Cell Disease Association. This association was founded in 1971. It has been continuously engaged with this issue since 1971, which incidentally was the same year that my cousin died of sickle cell

anemia in Opa-locka, Florida, Ms. Castor. She lived in southern Florida and also suffered from this disease. I ask that this letter be included in the record.

The Chairman. Without objection.

[The information follows:]

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

Mr. Butterfield. Mr. Chairman, as a cosponsor of the bill in this Congress and in previous Congresses, I have been a longtime advocate for addressing sickle cell. This disease is the most common genetic blood disorder. It affects approximately 100,000 individuals, primarily African Americans, throughout our country.

Imagine a child, Mr. Chairman, experiencing the most excruciating pain that one can feel. The child cannot think of anything except for wanting to stop her pain. The child's parents are terrified and they take the child to the emergency room. The child receives pain medications, often opiates, and is then discharged. Now imagine that over and over the pain could resurface at any time at home, school, or even on a family trip. The health challenges facing people with sickle cell disease are enormous.

The disease, Mr. Chairman, as we all know, is widespread, the consequences can be devastating. People with sickle cell disease have a much shorter life expectancy with men expected to live until age 33 -- yes, 33 -- women to age 36. These patients are more likely to have additional health complications including stroke, blood clots, loss of vision, and lung and kidney failure. There are approximately 4,400 people with sickle cell disease right there in my home state of North Carolina. My hope is that someday there will be none.

But we will only be able to get closer to a cure if we support

beneficial programs like the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act. This bill reauthorizes that program, the Sickle Cell Disease Treatment Demonstration Program. It enables the secretary of HHS to support research to increase our understanding of the disease. It creates a grant program to study the prevalence of sickle cell and identify ways to prevent and treat sickle cell disease effectively.

This bill is a step forward in improving sickle cell care, but we must also consider additional ways to help patients with this rare disease. I have worked with my friend, Congressman Mike McCaul from Texas, to pass the Advancing Hope Act into law, extend the pediatric priority review program at the FDA, and to enable sickle cell disease to qualify as a rare pediatric disease. In fact, several weeks ago, the FDA granted the first rare pediatric disease designation to a treatment for sickle cell.

That Mr. Chairman is a big deal and I think Dr. Burgess would agree. We should do all that we can to learn more not just about sickle cell disease but also the sickle cell trait. There is a difference. We also must invest in federal programs that research sickle cell disease like those funded by NIH and for treatment like cord blood banks. We should explore ways to reduce emergency room utilization for sickle cell patients that cost an estimated $2-1/2 billion. We must also consider ways to increase funding for sickle cell research at academic centers that conduct

clinical studies.

Sixty five percent of individuals with sickle cell disease in my little state of North Carolina have at least one emergency room visit per year. That is no way to live, and I can just imagine the number of visits in a state like California or Texas. We should do all we can to help improve patients' lives, advance treatment, and find a cure.

I am grateful for the opportunity to move this bill through the committee process and I hope that all of you, my colleagues, will join me in supporting it. Thank you for the time. I yield back.

The Chairman. I thank the gentleman for his commitment to this cause and this legislation and your kind comments, and we are all together trying to move this forward and get cures. We all have these issues. So with that the gentleman yields back the balance of his time.

Other members seeking recognition on this piece of legislation? If not, the question now occurs on favorably reporting H.R. 2410 to the House.

All those in favor will signify by saying aye.

Those opposed, no.

The ayes appear to have it. The ayes have it and the bill is favorably reported.

The chair calls up H.R. 2430, as amended, by the Subcommittee on Health on May 18th, 2017, and asks the clerk to report.

[The Bill H.R. 2430 follows:]

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

The Clerk. H.R. 2430, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee programs for prescription drugs, medical devices, generic drugs and biosimilar biological product, and for other purposes.

The Chairman. Without objection, the first reading of the bill is dispensed with. The bill will be open for amendment at any point. The chair now recognizes himself for purpose of offering a bipartisan amendment and the clerk will report that amendment.

The Clerk. Manager's Amendment to H.R. 2430 offered by Mr. Walden.

[The Manager's Amendment offered by The Chairman follows:]

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

The Chairman. The bipartisan amendment makes a number of changes to several of the amendments that were adopted at the Health Subcommittee. I want to thank Ranking Member Pallone and my colleagues on both sides of the aisle for continuing to work through these issues over the past couple of weeks to improve the language in the bill reported out of the subcommittee.

Changes to the over-the-counter hearing aid language include strengthening the labeling requirements to ensure these products are solely intended for adults and so the consumers have scientifically valid, FDA-approved information on symptoms that should prompt them to seek professional care. In addition, this amendment includes changes Representative Schrader and Bilirakis have worked tirelessly on to improve their legislation that will increase timely patient access to lower cost generic drugs, to increase competition, and to put an end to these egregious price hikes for older drug products that have long ago lost patent protection and are subject to exploitation by bad actors.

Indeed, today we have an opportunity to move legislation forward that deals with drug prices. With that I yield back the balance of my time and I recognize the gentleman from New Jersey to strike the last word.

Mr. Pallone. Thank you, Mr. Chairman. I want to speak in support of this bipartisan amendment offered by yourself and me. This bipartisan amendment makes a number of technical edits and other changes to three of the amendments that were adopted during

consideration of the FDA Reauthorization Act at the Health Subcommittee.

The changes included in the manager's amendment will help to strengthen the over-the-counter hearing aid legislation offered by Representatives Kennedy, Blackburn, and Carter by enhancing the labeling requirements to make clear that over-the-counter hearing aids when developed are intended for adult populations. Such labeling will also include information regarding the symptoms or conditions that should prompt consultation with a physician.

We have also clarified in the legislation offered by Ranking Members Green and Burgess and Representatives Lance and Dingell that penalties related to counterfeit drugs will apply to those making, selling, or dispensing counterfeit products.

And finally, we worked with Representative Schrader and Bilirakis to make improvements to their legislation to encourage generic competition in the marketplace through carefully targeting limited exclusivity to sole source products without generic competition, narrowing eligibility for the Tropical Disease Priority Review Voucher to treatments that contain new clinical investigations, and examining the factors that may be impeding the approval of generic applications in the first cycle. These changes make improvements to bipartisan legislation that has been supported by the members of this committee and outside stakeholders and I urge my colleagues to vote in support of the

manager's amendment and I yield back.

The Chairman. Is there further discussion on the amendment on the Republican side? We will look toward the Democratic side now and Mr. Doyle is recognized to strike the last word.

Mr. Doyle. Thank you, Mr. Chairman. I move to strike the last word. Mr. Chairman, right now our country is in the middle of an opioid epidemic. Drug overdoses are now the leading cause of death among people under 50, and my region including Pennsylvania, Ohio, and West Virginia is at the epicenter. I don't know anyone who hasn't been touched in a personal way by this crisis.

The goal of these user fee agreements, and specifically the prescription drug user fee agreement, is to see that the pharmaceutical industry and the FDA work together to get high quality drugs to the marketplace quickly. Right now there are successful drugs that can save someone's life by reversing an overdose through injection or intranasal delivery. We need more of these truly lifesaving drugs on the marketplace, not less.

The FDA should prioritize approving these high-need opioid reversal drugs so that they are safe and affordable for the individuals and the first responders who rely on them. Intranasal delivery reversal drugs truly mean life or death for individuals and families. I hope that the FDA will apply fair, consistent standards to make sure that no family suffers the loss of a loved one needlessly, and I support the manager's amendment.

The Chairman. I thank the gentleman for his comments and his good work on this legislation. Are there other members seeking recognition? The chair recognizes the gentleman from Georgia, Mr. Carter, for 5 minutes to strike the last word.

Mr. Carter. Thank you, Mr. Chairman. Mr. Chairman, legislation and efforts being made to increase access for over-the-counter hearing aids will benefit millions of Americans. Currently, just six hearing aid manufacturers sell 98 percent of all hearing aids worldwide, reducing competition and stifling innovation and new ideas. With the current structure, hearing aids can cost thousands of dollars per hearing aid.

As a result, nearly 80 percent of the people that would benefit from hearing aids don't use them. In addition, Medicare doesn't cover the cost of those hearing exams, hearing aids, or hearing aid fittings. Something has to change. That is why this legislation is so important to open up market access, increase competition, and actually bring more people to pursue hearing aid assistance. It will also be an opportunity and involve small businesses, and tens of millions of people who need hearing assistance will begin to enter the market.

As before, the FDA will continue to safeguard the needs of people with the same level of oversight as currently dispensed products. Finally, the current delivery system will be preserved allowing the people more options that better may align them with their financial situations.

In short, this legislation will utilize free market principles to drive down costs, open up opportunities for consumers, and allow for greater innovation in the hearing aid space. I commend my colleagues and committee for their hard work in this legislation and I yield back.

The Chairman. The gentleman yields back the balance of his time. The chair recognizes the gentlelady from New York, Ms. Clarke, for 5 minutes to strike the last word.

Ms. Clarke. Thank you once again, Mr. Chairman. Mr. Chairman, I rise in support of H.R. 2430, as amended, by the manager's amendment. This bill reauthorizes the FDA's user fees program which provides the FDA with much needed resources to review and approve new drugs and medical devices in a safe, efficient, and expedited manner. By doing so, it gives patients speedier access to often lifesaving drugs.

However, having a safe and speedy drug approval process means nothing if people do not have access to much needed medications. In fact, many of my constituents end up in the hospital emergency rooms because they can't afford their medications. I have no problem with a company making a fair and reasonable profit off their products, the key words here being fair and reasonable.

Last year, total spending on prescription medications surpassed $309.5 billion with the cost of some drugs jumping as much as 3600 percent over 2 years. These increases are happening at the same time that drug manufacturers are spending over 50

percent of their budget on advertising, not on new drug research and development.

Though this bill does little to lower drug prices, I will support it because it helps millions of Americans who are suffering daily, many of whom are at death's door. And unlike the drug companies' CEOs, I want to have a clear conscience when I go to sleep at night. I yield back the balance of my time, Mr. Chairman.

The Chairman. The gentlelady yields back the balance of her time. Are there other members seeking recognition? I was looking on this side, appears not. The chair recognizes the gentleman from Oregon, Mr. Schrader, for 5 minutes to strike the last word.

Mr. Schrader. Thank you very much, Mr. Chairman. I would also like to thank you and Mr. Pallone for working so well and so hard across the aisle to get us this far in this process for reauthorizing the critical drug and device server user fee programs, here, at FDA.

I would like to take a brief moment to mention the Generic Drug Access and Competition Amendment, which I offered in the subcommittee markup, which now makes up Title 7 of the Authorization Act.

At our subcommittee meeting I spoke about a constituent of mine, Susan, who saw the cost of the drug that kept her alive increase from $600 a month to $22,000 a month all over a short

period of time. Drug didn't go up because it was innovative, it didn't go up because there was a shortage or even a change in the marketplace, the drug had been around since 1985.

The only thing that had changed was that the drug manufacturer, Valeant, decided to put profits far ahead of any responsibility that they might remotely have for their patients and let greed act as their business model. Because this drug was meant to treat a rare disease, there is no competitor and there is nothing that could force prices down.

As I said also at our earlier meeting, this isn't the first time we have heard about this sort of thing. The last couple years, you all remember Turing and Martin Shkreli raising drug prices over 5,000 percent in one night. It couldn't be clearer that Congress needed to do something about this. And I was pleased to work with my good friend and colleague Bilirakis across the aisle to make some changes that we now incorporate.

The amendment created a new competitive generic therapies program at the FDA to get first generics and other generic therapies to market faster. It also improved the transparency at the FDA, studied ways to get more first-cycle approvals for efficiency's sake, and create incentives that the chair and others have alluded to, to encourage competitors to come to market, include presubmission hearing meetings, priority access and consultation throughout the process to make it go smoother, and 6-month exclusivity.

We also worked to strengthen the program integrity in our Tropical Disease Priority Review Voucher Program to bring it in line with congressional intent by ensuring the incentives we provide cannot be gamed and are only available to first competitors that come to market and make sure that the GAO remains independent in studying ways to improve the drug approval process.

Again Mr. Chairman, I want to thank you for your support of our amendment, thank Mr. Pallone, Mr. Green, Mr. Burgess, and Mr. Bilirakis my good friend, for all the hard work in approving the amendment and getting it to where it is today. Thank you, sir.

The Chairman. I thank the gentleman for his comments and his leadership on this issue. We look forward to including this in the bill and moving this bill forward today. It is important work.

Are there other members seeking recognition on the Republican side? If not, we will turn to Ms. Eshoo is recognized for 5 minutes to strike the last word.

Ms. Eshoo. Thank you, Mr. Chairman, for holding this important markup including this portion of it on the user fee reauthorization that is before us today. I have said time and time again that the FDA user fee agreements are really critically important programs that have provided essential resources to the agency. They have brought about many improvements.

This is not just something that is on automatic pilot when it comes up for reauthorization. They have brought about

improvements in drug and device review timelines, patient involvement, and very importantly the culture within the FDA and they have very importantly advanced innovation.

I am really pleased that the full committee is considering the legislation today because it makes timely and important improvements to two programs that I am particularly proud of because I was the author of them and they have withstood the test of time, the Biosimilar User Fee Agreement and the Medical Device User Fee Agreement, more commonly known as MDUFA. Together with Representative Barton we authored the Biologics Price Competition and Innovation Act that paved the way for the Biosimilar User Fee agreement which we are considering today.

And during the subcommittee markup I raised my concerns with the issuance of final or revised guidance on biosimilar interchangeability being delayed until as late as 2023. That date keeps being pushed forward and I really don't think anyone wins with that so, but I wanted to raise that.

So today I would like to reiterate that it is imperative. I think it is imperative. I think all the committee members think it is imperative that the FDA work in timely manner to release the interchangeability guidance that is critical for the nascent biosimilars industry. This is an American industry not a foreign industry that we are advancing, and I think that the science that is foundational to this is essential for more breakthroughs for cures and help for the American people.

Now when we last reauthorized MDUFA in 2012, the medical device center was struggling with backlogs and presented many opportunities for improvement. The last MDUFA put the device center on the right track and I think it has been successful in increasing the efficiency of the device center in reducing the time it takes to bring effective medical devices to the U.S. market.

So I think these programs are examples of legislation that have worked and worked well, so reauthorizing the user fee agreement is really one of the most important efforts that our committee will undertake this year.

I think, Mr. Chairman that there might be I don't know, as I understand it an amendment that is raised that really has not been vetted, has not gone through the committee process and all of that. I am just going to say out loud please don't do that. Please don't do that.

Don't risk -- for all the years that I have been on this committee since 1995 we have always have had a clear, transparent pathway for the reauthorization without any sand being thrown in the gears and I would ask that we stay on that path. We have a lot of important bills here and it usually is taken up on the suspension calendar. I don't think you want all the Democrats voting against it and having it go down on the suspension calendar. That is just not good sense, so I would just ask that that not happen.

I think also that because it is a must-pass bill the words "pink slips" may not mean that much to anyone around here, but just put yourself in the shoes of someone that is over at the FDA. And we demand the best of that agency. We are not going to get it if there are pink slips that are issued.

So that, I think, is kind of the 10,000 pound elephant in the room, but I think that we can usher the elephant out and get the bill done in a clean way, transparent way, and move on. So thank you for calling on me and I hope that you will take my call for the consistent bipartisanship without complication that we have always operated under. It has served us all very well. Thank you and I yield back.

The Chairman. I thank the gentlelady for her comments and I look forward to continuing to work with her on this and other issues. Other members seeking recognition? I think I go to Mr. -- oh, no. Mr. Kennedy is next, right? I want to get the seniority right down there.

Mr. Kennedy. Thank you, Mr. Chairman.

The Chairman. The nearly Republican, I mean you are just that close, so close, recognized for 5 minutes.

Mr. Kennedy. It is an optimistic world, Mr. Chairman. Yes, thank you. I am working on Mr. Bucshon though, slowly but surely. Mr. Chairman, and to the ranking member as well, thank you for all your work on bringing this bill to the floor before us today. I especially want to thank the staff and my staff who work

tirelessly behind the scenes.

My district is home to countless life science businesses that rely on their collaborative work with FDA to bring safe, effective drugs and devices to market and this legislation has been the foundation of that partnership and the innovation that drives a Massachusetts economy.

Walking across laboratory floors throughout my district and across Massachusetts, the belief that no disease is incurable becomes, yes, contagious. For the researchers on the front lines of medical innovation there is no vaccine, treatment, or device that is out of reach. And despite persistent setbacks and doubt that would make many of us crumble, these modern pioneers relentlessly pursue lifesaving cures for patients that they will never meet.

But in order to make their dreams a reality it is critical that the FDA is adequately staffed and funded. Combined with 21st Century Cures and a continued commitment through bipartisanship and bipartisan support for NIH funding, this reauthorization legislation will not only strengthen protections for patients but accelerate the pace of medical research. And it is the same mission that lies at the heart of the over-the-counter hearing aid bill on which I was pleased to partner with Representative Blackburn.

The hearing aid legislation in this bill will make hearing aids more affordable, more accessible, and more innovative. The

manager's amendment includes a few technical fixes to the hearing aid language including more specific labeling requirements to ensure that these over-the-counter devices are intended for adults only and the labeling will direct people with medically treatable hearing loss to consult with a doctor. In addition to study that the secretary of HHS will conduct, the technical fixes include language ensuring consumer rights and protections.

Facing costs of nearly $5,000 for a full set of hearing aids, millions of Americans simply forego treatment. With the support of consumers, doctors, industry, the FDA, and AARP, this bipartisan legislation would dismantle barriers that continue to confront seniors around our country.

But its benefits extend far beyond the oldest generation. Just this week a friend of mine wrote to me to share her own story. As a 34 year old lawyer her hearing loss left her unable to continue her career in a courtroom. Because insurance won't cover hearing aids she has faced nearly $20,000 in less than a decade. Fortunately, she can afford them, but millions of others cannot. In her words she says, quote, I can't tell you the number of people who confide in me about their own undiagnosed hearing loss after I mention mine. It is unbelievable and really sad.

I am sure you know this, but there has been research showing that untreated hearing loss leads to social anxiety, depression, et cetera, which makes sense. If you can't hear you can't engage and you are essentially excluded from conversation. I get very

frustrated when I can't hear parts of conversations and I know how annoying it must be for others to have to hear me squawking what at every other sentence. The articles I have read also say it is likely to lead to early dementia and more. I know I am preaching to the choir, but I am happy to be a resource for anyone who needs any ammunition before this vote.

And if left untreated, those with hearing loss will suffer through devastating health, social and economic consequences. Through the innovation and competition already available taking place across our country we can begin to ease the burden for countless Americans of all ages, backgrounds, and incomes. With the FDA's assurance for safety and efficacy, with clear labeling, and with proper volume output limits, these devices will be able to safely bring relief to our relatives, our colleagues, our neighbors, and constituents whose suffering has been overlooked and unseen for far too long.

I support this manager's amendment and would yield my time to anybody that would like it.

Mr. Murphy. Mr. Kennedy, would you yield a moment to me?

Mr. Kennedy. Yes, please.

Mr. Murphy. I want to thank you for also pointing out in that very moving letter that the issues you described there are people with sensory loss as with all other chronic illnesses that the risk for depression and other mental illnesses is double that of the general population and with something untreated it doubles

the cost. Something as simple as this, to bring a person's sensory back to the world around can make a huge difference and otherwise we end up paying in other ways for it. So I thank you for highlighting that. Thank you. I yield back.

Mr. Kennedy. I yield back as well. Thank you.

The Chairman. The gentleman yields back. Are there other members seeking recognition? The chair now recognizes the gentleman from California for 5 minutes.

Mr. Ruiz. Thank you, Mr. Chairman. As a physician and like everyone else on this dais I know that the FDA plays a critical role in ensuring patients are kept safe. The FDA gives people the peace of mind to know that the drugs they are taking and the devices they are using won't have harmful effects, and without an effective and efficient approval process people would not have access to the medicines that they need. That is why these user fees agreements are so important, to ensure the FDA can improve their process to more efficiently approve innovative products and keep our medicines safe.

This is precisely why we must come together in a bipartisan fashion to solve this issue so patients are not forced to go without the lifesaving treatments that they need. New medicines that provide better treatments are important and so is the safety of those drugs and the peace of mind Americans have developed knowing that the FDA prioritizes drug effectiveness and safety. For these reasons we must pass a clean version of this bill.

Instead of offering last-minute, vague, or partisan-type amendments that may jeopardize the overall bipartisan nature of this bill, let's come together to solve this problem; get something done for the American people.

I also highly encourage that we come together in a bipartisan way to find pragmatic solutions to lower the cost of medications overall for all Americans, to hold more hearings to make sure that Americans can afford the medications that are proved by the FDA in a manner that will be life changing for our patients. With that I yield back my time.

The Chairman. The gentleman yields back the balance of his time. Are other members seeking recognition? Finally, we get to the gentlelady from Michigan, Mrs. Dingell, for 5 minutes.

Mrs. Dingell. Thank you, Mr. Chairman -- I know my role in life and rank -- and to the ranking member. The manager's amendment makes a technical correction to the Drug Diversion and Counterfeit Crackdown Act which was included in the subcommittee level, and I just want to say a few words about the importance of this provision which I was also very proud to work with on a very bipartisan way with Mr. Lance, Dr. Burgess, and Mr. Green.

We all really care about this issue. I mean we all, we are sitting here today because we all know Americans are paying too much for drugs and we are each hearing these stories. I hear them every day from picking up John's medicine at Cherry Hill Pharmacy to the senior centers we go to and the seniors that are just in

tears because they can't even afford their insulin.

So Americans have to have that peace of mind though in knowing that the drugs they buy are safe and they are not going to cause them harm. Unfortunately, the threat of counterfeit and diverted prescription drugs remains a real threat to the American consumer. If you go online you can easily find many online pharmacies selling drugs at very low prices that seem to be too good to be true.

And yet if you are desperate you go to that site because you need your medicine and sometimes you can't afford your medicine and your food. Sadly, this is oftentimes true because the drugs are too good to be true. They are counterfeit or made with the incorrect amount of active ingredients.

We must make every effort to ensure that our drug supply chain is as secure as possible and that we are doing everything we can to deter bad actors. This provision closes a loophole in the current law by strengthening penalties for selling counterfeit and diverted drugs to help prevent this market from growing. I am honored to work with this committee for this common sense step to improve the security of our drug supply chain and look forward to continuing our work together in this important area. I yield back the balance of my time.

The Chairman. I thank the gentlelady for her good work and for her comments. If there is no further discussion the vote occurs on the manager's amendment, the Pallone-Walden, Walden-Pallone amendment.

All those in favor shall signify by saying aye.

Those opposed, nay.

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

Are there further bipartisan amendments? Mr. Peters?

Mr. Peters. Mr. Chairman, I have an amendment at the desk.

The Chairman. The clerk will report the amendment.

The Clerk. Amendment to H.R. 2430 offered by Mr. Peters.

[The Amendment offered by Mr. Peters follows:]

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

The Chairman. The reading of the amendment is dispensed with. The gentleman is recognized for 5 minutes to speak on his amendment.

Mr. Peters. Thank you, Mr. Chairman. This amendment creates a clear, predictable FDA regulatory pathway for new imaging procedures that use approved contrast agents. Contrast agents are drugs that are injected before some medical imaging procedures to enhance the quality and the clarity of the image and innovations in medical technology have led to new uses for many previously approved contrast agents.

But the regulatory process, as often happens, for making sure all healthcare providers know of these advances has been unclear. This often requires a re-approval of the contrast agent to update the label even when the only change in the procedure is the body part being imaged. This has slowed the approval of innovative, new imaging procedures that have the potential to better diagnosis and help patients.

Our amendment clarifies that the FDA can modernize and streamline their approval process for the use of contrast agents in medical imaging. It will make groundbreaking procedures available to patients more quickly and support innovation in the medical imaging arena that creates high paying jobs and grows the economy in places like my district in San Diego.

I want to thank Mr. Costello for partnering on this amendment which we originally introduced as a standalone bill and also the

ranking member and chairman for their support. I yield back.

The Chairman. The gentleman yields back. Are there other members seeking recognition on this amendment?

Mr. Costello. Mr. Chairman, I would move to strike the last word.

The Chairman. The gentleman is recognized for 5 minutes.

Mr. Costello. I want to thank Mr. Peters for his work on this effort and in particular our committee staff who helped make sure this important straightforward step would be addressed in this legislation. We just heard from Mr. Peters in great detail the background and need for this policy. I would just like to quickly build on his remarks.

This amendment would encourage the adoption and acceleration of the latest innovation in medical imaging. It would allow the FDA to keep pace with advancements in new diagnostic tools that offer patients and physicians more precise and accurate information. The common theme today is advancing medical innovation and delivering safe and expedient technologies to patients and providers, and this amendment fits that exactly.

Again I thank Mr. Peters for his work with me on this effort and I encourage all my colleagues to support this amendment. I yield back.

The Chairman. The gentleman yields back the balance of his time. Are there other members seeking recognition?

Seeing none, the question now arises on passage of the

amendment.

All those in favor will say aye.

Those opposed, nay.

The ayes appear to have it. The ayes have it and the amendment is adopted.

Are there other bipartisan amendments to be offered?

The gentleman from Pennsylvania, for what purpose do you seek recognition?

Mr. Costello. Mr. Chairman, I would like to introduce an amendment on behalf of myself and my colleague Mr. Peters.

The Chairman. The clerk will report and distribute the amendment.

The Clerk. Amendment to H.R. 2430 offered by Mr. Costello.

[The Amendment offered by Mr. Costello follows:]

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

The Chairman. Without objection, further reading of the amendment is dispensed with. The gentleman from Pennsylvania is recognized for 5 minutes to speak on his amendment.

Mr. Costello. Mr. Chairman, our amendment is the result of a bipartisan dialogue focusing on addressing concerns about the quality, safety, and efficacy of medical devices that have been subject to repairs, refurbishing, and reconditioning by third parties. These concerns are nothing new. Improperly serviced medical devices can lead to malfunctions that could cause a misdiagnosis or a missed diagnosis which could cause care to be delayed or worse -- lead to severe patient injury or death. For example, if an x-ray image is fuzzy or blurred due to poor calibration a fracture could be missed, or if the magnet in an MRI machine is not properly vented pressure can build up inside the magnet resulting in eventual explosion.

In the case of ultrasound and other devices, if the device has not been properly sealed as part of servicing activities, patient infection could result. In fact, stakeholder concerns regarding improperly serviced medical devices, in particular radiation-emitting devices, prompted the FDA to take action in early 2016 to solicit comment and feedback on this very topic.

Under current law, medical device service and maintenance activities that are provided by the original equipment manufacturers are subject to FDA regulation. However, these same activities performed by third parties have no FDA oversight and

as a result are not held to any quality, safety, and regulatory requirements.

That is why earlier this year, Congressman Peters and I introduced H.R. 2118, the Ensuring Patient Safety through Accountable Medical Device Servicing Act, to provide the FDA with information that is vital to the safety of medical devices including endoscopes, infusion pumps, and radiation-emitting devices. This bipartisan legislation was featured earlier this year during a Health Subcommittee hearing, and as a result of feedback and concerns raised during that hearing we have worked tirelessly with our colleagues, committee staff, and stakeholders to craft this amendment today. What does the amendment do?

This amendment sets forth a plan of action for the FDA to complete its work on this issue and outline what must be done in order to ensure the quality, safety, and continued effectiveness of medical devices. This amendment would require the FDA to report back to our committee outlining the comments and feedback it has received over the past year and a half as well as details on the steps that the FDA believes we can take in order to protect the public health and ensure that medical devices which have undergone service, maintenance, and refurbishing maintain the same high standards of quality as initially certified by the FDA.

It is important to note that this amendment does not impose any new requirements on third-party servicers. This amendment simply continues the conversation and fact-finding effort that

the FDA started in early 2016 and offers a simple preventive solution that will move us closer to providing patients and providers with greater accountability and transparency.

Patients should not be forced to take a leap of faith about the upkeep of medical devices. I thank my colleagues and our committee staff for working to find a solution that will help us provide patients the peace of mind they deserve and yield back.

The Chairman. The gentleman yields back the balance of his time. Are there other members seeking recognition? The gentleman from California is recognized to strike the last word.

Mr. Peters. Mr. Chairman, thank you very much. I would like to thank Mr. Costello for his leadership and partnership on this effort. The amendment that we offer today directs the FDA to assess the issues surrounding service and maintenance of medical imaging equipment and report back to Congress. I would rather that we were considering a stronger measure similar to the bill that we introduced earlier this year that Mr. Costello referenced to direct the FDA to create a registration process for third-party servicers, but this amendment is definitely a step in the right direction and will help put us on a path that will ensure patient safety and provide peace of mind that imaging equipment works the way it is intended to work.

Thank you to the chairman and the ranking member for their support and again to Mr. Costello for his bipartisan partnership on this. I urge my colleagues' support and yield back.

The Chairman. The gentleman yields back the balance of his time. Further discussion on the amendment? Seeing none, the question now comes before the committee on approval of the amendment.

Those in favor will say aye.

Those opposed, nay.

The amendment is adopted.

Are there other bipartisan amendments? Mr. Welch, for what purpose do you seek recognition?

Mr. Welch. I do. Thank you, Mr. Chairman. I have a bipartisan amendment at the desk --

The Chairman. All right, the clerk will --

Mr. Welch. -- with Mr. McKinley.

The Chairman. The gentleman will suspend. The clerk will report the amendment. It is Welch 1.

The Clerk. Got it. Amendment to Committee Print of H.R. 2430 offered by Mr. Welch of Vermont.

[The Amendment offered by Mr. Welch follows:]

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

The Chairman. Without objection, further reading of the amendment is dispensed with. The gentleman from Vermont is recognized for 5 minutes to speak on his amendment.

Mr. Welch. Thank you, Mr. Chairman. I do plan to withdraw the amendment after debate, but I hope that this committee will work to pass this bipartisan legislation in the near future. I want to thank my colleague Mr. McKinley for working very hard on this with me.

A little background, the Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require Risk Evaluation and Mitigation Strategy, REMS, to ensure that the benefits of certain drugs or biologic products outweigh their risk, and that was obviously a concern about safety.

And while that was intended as a safety measure, it is unfortunate that some drug manufacturers have been really exploiting the REMS requirements to delay generic competition for both REMS and non-REMS products, essentially trying to hang on beyond the legitimate life of their exclusivity period, the benefit of that higher pay they are going to get.

Specifically, companies are misusing restricted distribution network requirements to deny generic and biosimilar manufacturers' access to the product samples that they need to get FDA approval. And these biosimilar companies can do real good to get these products out to people who need them and help us to bring down cost, so we want to make sure this process is fair and

it is not abused.

Our amendment, Mr. McKinley and I, would close the loopholes. It would address the most common abuses of REMS and non-REMS restricted access programs. It is identical to our legislation, the FAST Generics Act that addresses this issue. The Congressional Budget Office estimates that this proposal would save $2.8 billion. That is money that is great to save and we could do it.

In addition to Mr. McKinley as co-lead, Representative Stivers and Representative Fortenberry are cosponsors.

Just to give you an example, a case study. Celgene delayed access to Thalomid and Revlimid samples despite the explicit FDA authorization and requirement to get that product out. Celgene did use our REMS loopholes to delay providing samples to generics for almost 4 years between 2007 and 2011, and during that 4-year delay, Celgene successfully shifted the vast majority of their multiple myeloma patients to its follow-on product Revlimid. That generated about 3.5 billion in revenues. And now what we are seeing is a repeat of that delay tactic as applied to Revlimid.

So bottom line here, it is great that a company that comes up with a product gets an exclusivity period so that they can get a return on their investment. They are taking a risk and we get that. What is not great is when they basically game the system to extend that exclusivity period Congress has granted in order basically to keep market power pricing of almost a monopoly on

a product where that exclusivity period is expired, and it thwarts the really good work of our generic or biosimilar manufacturers who want to help our patients.

So this is something that we are not going to take up today, but down the line working together, Mr. McKinley, I hope we can see this gets passed in the future.

Ms. DeGette. Will the gentleman yield?

Mr. Welch. I will yield. I think it was to Mr. Cardenas first.

Mr. Cardenas. I will just use a few seconds. I just want to say thank you to my colleague Mr. Welch from Vermont. Nobody takes up more of my time and energy and rightfully so on this particular issue other than my constituents who definitely want us to do the right thing and address this very important issue. So thank you for bringing it up and we look forward to having the hearings in the future and thank you for your diligence. I yield back.

Ms. DeGette. Will the gentleman yield? It is me.

Mr. Welch. If I have any time I yield to Ms. DeGette.

Ms. DeGette. Thank you. I just want to reiterate the importance of this issue and speak in support of the McKinley-Welch amendment. What this would do is it would really reduce barriers to bringing lower cost generic drugs onto the market. This is an issue that we worked extensively on with 21st Century Cures. We weren't able to get it into the final version,

but I think it is great public policy and I want to thank the gentleman for offering it. I yield back.

The Chairman. Everybody yields back, okay. The gentleman's time has expired. Are there other members seeking recognition? The gentleman from West Virginia is recognized to strike the last word.

Mr. McKinley. Thank you, Mr. Chairman. I just want to reinforce some of what my colleague Mr. Welch was just referring to on this legislation that brand name pharmaceuticals have anywhere from 5 to 12 years to protect their product before the generic competition can set in. So they have 5 to 12 years to recoup their R&D, make their profits, whatever is appropriate, and then they expire and then the generics are supposed to have the opportunity to take off after that.

But what has happened is that, and I think that is what Mr. Welch was trying to express and I will try as well, is the pharmaceuticals that have the lead on that drug are not cooperating and allowing the generics to have access and they are dragging out the process. And as a result there are penalties built into this existing statute right now that they are supposed to be fined, but what we found out through the FDA no fines have been levied yet. After all this time none have been levied. And even those the way that they have assigned the values they are so low that the pharmaceuticals can still pay the penalties because the amount of the money they are making on the main drug

will offset that so it is built in to allow it to continue with it.

So this whole idea of allowing people to have access to it is long overdue and I think it is one that people have to realize without this, as long as people can drag out 3, 5 or years longer in not being able to have a generic, the patients, the individuals, the consumers out there are paying thousands of dollars more annually for some of their medicine that they could otherwise get and the federal government is being inundated with additional cost. Billions of dollars are going to be confronted with what they are paying for Medicare and Medicaid because of this high priced drug that should have been moved over to the generic sector.

So look, this thing is -- Mr. Welch and I have been working on this. Last year we were very close. There were some negotiations going on at the end of last year under the 21st Century Cures and it broke down at the end. So the matter here is when are we going to do this? When are we going to step up and say to the pharmaceuticals you have to stop, you have got to turn over, that is the law. That is the law. You are supposed to turn that over. So it is when are we going to fix this? If not now, when?

So Mr. Chairman, I am hoping we can get, if this is going to be withdrawn, as I understand it, it could very well be, let's at least, can we get a commitment that you will help us bring the pharmaceuticals back to the table so we can have a meaningful adult

conversation with them about how we can get the generics back to the market in a timely fashion without costing the federal government billions of dollars? Can you give us some assurance that you will help us?

The Chairman. You know, Mr. McKinley, as I mentioned to you earlier this morning I am happy to work with you on this legislation. There is some issues in it today that we felt needed some additional work, but as I conveyed to you earlier this morning, I am more than happy to work with you on this and other issues before the committee at any time to see if we can find common ground.

Mr. McKinley. Thank you. I yield back.

The Chairman. The gentleman yields back. The chair recognizes the ranking member, Mr. Pallone.

Mr. Pallone. I move to strike the last word, Mr. Chairman, and speak in support of the amendment offered by Congressman Welch and McKinley.

Americans of all political viewpoints agree that drug prices are out of control. According to the Kaiser Family Foundation, nine out of ten people are in favor of making it easier for generic drugs to come to market in order to increase competition and reduce costs. This committee has examined policies to encourage generic competition and we have made progress in helping to create more opportunities for manufacturers of first generics to engage with FDA throughout their development process and have created a

targeted period of exclusivity for sole source drugs.

However, we have not worked to address one of the largest barriers to generic competition, the anti-competitive tactic by some brand drug manufacturers to delay, deny, or otherwise impede access to samples of their drug products. These samples are needed by generic companies to conduct the bioequivalence studies needed to support approval. Certain companies have been inappropriately utilizing risk evaluation and mitigation strategy programs, or REMS, as an excuse to block competition, costing patients more than $5 billion each year and putting medications out of reach for millions.

REMS was intended as a safety measure in the drug approval process not as a tool to block competition, and this is a very real problem that has been acknowledged by both the FTC and the FDA. In a recent Bloomberg interview, current FDA commissioner stated that getting access to samples can be hard unless the branded companies are going to facilitate the ability of the generic companies to get the drug. They can't just go into the market and buy it readily.

Dr. Woodcock also testified this year that the agency has received more than 150 complaints that samples were being withheld from generic drug companies. And it is no wonder that companies are using REMS and restricted access programs to block competition. A recent analysis found that of the 74 drugs subject to REMS or restricted access, total sales for these products in

2016 was nearly $23 billion.

Unfortunately, current law does not provide a clear remedy when brand name companies restrict access to samples or refuse to negotiate shared safety protocols to delay generic entry, a problem that the amendment offered today by Representatives Welch and McKinley would address. The FAST Generics Act would take the important steps to fix this anti-competitive gaming of REMS. Specifically, the FAST Act would provide a pathway for generic drug companies to gain access to samples of brand drugs, limit the extent to which companies can delay competition, and help bring generic drugs to market sooner.

So the amendment offered today by Mr. Welch and Mr. McKinley will help to take the first steps to end the anti-competitive tactics by brand companies, promote competition in our pharmaceutical marketplace, and help to curb prescription drug costs for all Americans. So I would urge my colleagues to support this amendment. I know it is going to be withdrawn, but I certainly agree that this is something that we need to do. I yield back.

The Chairman. The gentleman yields back. Are there other members seeking recognition on this amendment? The chair recognizes the gentlelady from -- oh, wait. I am sorry. The chair recognizes the gentleman from Oklahoma, Mr. Mullin.

Mr. Mullin. I move to strike the last word. I would like to speak about the RACE for Children Act. All of us here today

have something in common. We represent children and patients and children who are fighting cancer without cures. The reality is there is far less drugs being made to help these children get better.

Along with Chairman McCaul and Congressman Butterfield, I want to reiterate my support for the RACE for Children Act which aims to fix the lack of cancer drugs available for children. RACE for Children puts safety first and assures that researchers use scientific evidence when declaring effectiveness of a drug and especially before providing it to patients.

Since I last spoke about this bill we have made changes to the bill that makes the bill even stronger. Our efforts have been bipartisan. We have taken industry, stakeholder, and FDA input into our legislation and we are working along all the players here to come with an agreement to get the bill passed and signed into law.

It is our hope to have the RACE for Children Act included during floor consideration of this bill and we will continue to work towards that goal. I look forward to working with Congressman Butterfield and my colleagues on this committee to get the RACE passed for every child hoping for lifesaving cancer treatments. And I thank the chairman and I want to yield the remainder of my time to Chairman Burgess.

Mr. Burgess. I thank the gentleman for yielding. And Congressman Mullin, I want to thank you for your work and the work

of our colleague Michael McCaul and Representative Butterfield on this important initiative. Members of this committee have a longstanding commitment to incentivizing and speeding medical innovation and Chairman Walden and I are dedicated to working with you on the RACE for Children Act before this bill, before this bill goes to the floor.

There is no cause more worthy than increasing the number of safe and effective treatments available to children battling cancer and I want to assure you that we are dedicated to advancing policy that will accomplish just that goal. I yield back to the gentleman from Oklahoma.

Mr. Mullin. I want to yield some time to my colleague Congressman Butterfield.

Mr. Butterfield. I would like to claim my own time if I can, Mr. Chairman.

Mr. Mullin. Then I yield the remainder of my time.

The Chairman. The gentleman yields back the remainder of his time. Actually, I need to recognize Ms. Eshoo for 5 minutes to strike the last word.

Ms. Eshoo. Thank you for recognizing me, Mr. Chairman. I move to strike the last word. First, I want to go back to the Welch-McKinley amendment. I understand, well, it is being offered, perhaps withdrawn. I have a different take on this. I think that the effort so far in terms of how it is drawn conflates samples issues with shared system REMS and I think that this needs

some more work because the bill as written really waives the requirement for a single shared system which raises very important issues about patient public safety issues.

I have had some experience with REMS and I have a good sense of where I think the authors want to go, but I think the way this is drafted really needs some more work.

The Chairman. Would the gentlelady yield?

Ms. Eshoo. I would be glad to.

The Chairman. I appreciate the gentlelady's comments. That was my comment to Mr. McKinley as well and I appreciate the authors' willing to offer and withdraw for this very purpose to keep this bill bipartisan and to work out these differences, legitimate differences, members of the committee have.

Ms. Eshoo. Good. Right. There are presently 42 drugs that have already shared, so I don't know what universe this draft amendment is going after. Is it five or is it two or is it one? But I do think that there is a conflation of those two issues and I think that more work needs to be done. And I would be happy to help and so I wanted to make a comment on that.

I also want to say a few words about the changes that are being made to my legislation, the Pediatric Research Equity Act, better known as PREA. Now before the BPCA and PREA, more than 80 percent of drugs used in children were used off-label without data on their safety and efficacy. And thanks to both the BPCA and PREA today that number has come down considerably.

Now at the subcommittee hearing last month I spoke about the significance of the program and the companion, the Best Pharmaceuticals for Children Act, and I reiterated my commitment to these programs that have resulted in new dosing information, new indications of use, new safety information, and new data on effectiveness. I said at that time children are not just, are not -- were being treated as essentially as small adults. Parents were being instructed to cut pills in half or in thirds in order to have dosage for them. And so we have gone a long way to improve that.

I also spoke about my willingness to work with people on this. Now, it is my understanding that the Senate has engaged stakeholders on ongoing negotiations regarding changes to PREA and that there are House colleagues that were invited to participate in the conversations. No one has ever contacted me. And I said at the subcommittee markup in the clearest, plainest, most sincere way these are my bills. I authored these. I think it would be wonderful to work with people on it and I have never heard from anyone.

So I think that you know I want to reiterate my offer. I don't know who is leading this up, probably the subcommittee chairman. I want to work with you on this. We have the responsibility obviously to periodically review these programs to make them better and I am all for that. I don't think there is anything that is on the books that can't be improved, but I

also would like to be a part of it.

And I believe that the user fees are an appropriate vehicle to consider changes to these programs, but once again I would like to be involved in it. So I hope that that will take place, Mr. Chairman.

The Chairman. Yeah, will the gentlelady yield? We would be delighted to do that.

Ms. Eshoo. Yeah.

The Chairman. I think it is really important work we can find common ground on. And I think Dr. Burgess can speak for himself, but I think he would agree as well, and Mr. Mullin and it is important to get this right, so.

Ms. Eshoo. Good. So I am prepared to yield back my time. I just wanted to reemphasize as I did at the subcommittee that I want to work with whomever is doing this. Now if this committee is -- I should say, in my understanding I have heard that this committee is going to accept whatever the Senate does and I think that we need to --

The Chairman. No, I don't believe that to be the case.

Ms. Eshoo. That is not the case? Good, okay. So I am here. I authored both of those bills. I want to work with you. Every bill can be improved, but I would like to be at the table with my colleagues and make sure that this remains bipartisan and a solid good bill for children in our country. Thank you and I yield back.

The Chairman. The gentlelady's time has expired. Are there other members seeking recognition? The gentleman from Florida, Mr. Bilirakis, is recognized for 5 minutes to strike the last word.

Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it. I would like to speak in support of the RACE for Children Act and I want to commend my colleagues, Markwayne Mullin and G.K. Butterfield, my good friends, for their good work, and their staffs, but also I want to commend the staff, the committee staff as well. They are doing a great job.

Pediatric cancer kills about 1,250 children under the age of 15 every year, and yet new and innovative cancer treatments are not given to children until years after adults receive them. That is just not right. The RACE for Children Act will address this problem by providing that drug companies study the most promising new cancer drugs not only in adults but also in kids.

In the Tampa area we have Moffitt Cancer Center, they do an outstanding job. They are the only national cancer institute designated comprehensive cancer center in the state of Florida. Last Congress we had Dr. Sellers, Moffitt Center director, participate in one of the 21st Century Cures roundtables in my district. He talked about how cancer research has evolved and how doctors moved away from targeting specific body parts to targeting specific cancer molecules.

The RACE for Children Act is a reflection of how cancer

medicine has evolved. Adult and pediatric cancers share the same molecule targets, meaning that a new cancer drug could exclusively target those cancer molecules no matter the patient's age. It makes sense to study that cancer drug's effect within a pediatric population.

This update to the 2003 Pediatric Research Equity Act will increase the level of pediatric cancer studies. For the over 10,000 kids, 10,000 children in the U.S. under the age of 15 who will be diagnosed with pediatric cancer this year we must get this done. I know that we are not quite there yet, but hopefully we will be there on the floor of the House of Representatives. So I appreciate my good friends, again Mr. Butterfield and Mr. Mullin, for offering this amendment. I know it is going to be withdrawn today, but let's get this done. And I appreciate all your efforts, appreciate it very much and I yield back. Thank you, Mr. Chairman.

The Chairman. The gentleman yields back. Are there other members seeking recognition? The gentlelady from Illinois is recognized next, Ms. Schakowsky.

Ms. Schakowsky. Thank you. I will be brief. I support this amendment. I am very proud to be a cosponsor of the FAST Generic Act sponsored by Congressman McKinley and Welch. We have all agreed, I think, today that an overwhelming majority of Americans support policies that make it easier for generic medications to come to market. However, brand name corporations

continue to engage in anti-competitive behavior that impedes the development of generics and biosimilars. In fact, the Federal Trade Commission has on two separate occasions argued that such practices violate antitrust laws.

This amendment would limit the ability of brand name manufacturers to engage in those harmful behaviors which in turn would aid in the development of generics and biosimilars. The Congressional Budget Office estimated that this legislation would save taxpayers more than $3 billion. So I strongly believe that this is common sense legislation. Every member of this committee should be able to support it.

I applaud my colleagues for offering this amendment and I want to also echo Representative McKinley's plea that if we don't have a vote on this bill that this amendment doesn't pass that we definitely need to have the full committee discuss this much further, and I thank you and yield back.

The Chairman. The gentlelady yields back. Are there other members seeking recognition? The gentleman from Texas, Mr. Barton, is recognized for 5 minutes to strike the last word.

Mr. Barton. Well, thank you, Mr. Chairman. And thank you and Mr. Pallone for this bipartisan markup of many bills that need to be moved. I want to add my voice to the numerous others that have already spoken about the bill that we call the RACE for Children Act. Congressman McCaul from my home state is a big supporter of this as on the committee we have Mr. Butterfield,

Mr. Mullin, Mr. Bilirakis, and myself.

And I was led to believe that Ms. Eshoo was onboard and apparently she is not. Let's get that worked out, you know, so we can move this. And I think, Mr. Chairman, we have your commitment that we will continue to work on it and so that we can -- I was led to believe we were going to add it today, but if we need to wait let's wait, but let's get it done. So I am very supportive of it.

The Chairman. The gentleman yields back the balance of his time. The chair now recognizes the gentleman from North Carolina, Mr. Butterfield.

Mr. Butterfield. Thank you, Mr. Chairman. I move to strike the last word. First, let me start, Mr. Chairman, by thanking Mr. Mullin and Mr. Bilirakis for their kind words but, more importantly, thank them both for their passion on these issues.

I am proud, Mr. Chairman, to represent a remarkable young man who was treated at Duke University Medical Center in my district. His name is Hunter Pietrowski. Hunter is 14 years old, and all of us, many of us have had 14 year old children. Hunter is 14 years old and was diagnosed with a brain tumor. He had a stroke and then beat his brain cancer.

Hunter should have been playing basketball, swimming, enjoying life with his friends; instead he underwent multiple daily radiation treatments and four rigorous chemotherapy treatments. No child should have to endure such pain. I pray

that Hunter's health continues to improve and we can and must do better.

In 2012, as part of the last FDA user fee agreement, I put forward the Creating Hope Act, pediatric priority review voucher bill to address the scarcity of drug development for children with life-threatening illnesses. And I am proud to say today that Congress passed the Creating Hope Act in 2012 as part of the last FDA user fee agreement and reauthorized it last year as part of the 21st Century Cures Act.

Today I am committed to alleviating the plight of sick children like Hunter with the Research to Accelerate Cures and Equity for Children Act, a bill with strong bipartisan support that has eight members of this committee as cosponsors. The RACE for Children Act would update the Pediatric Research Equity Act so that companies developing novel and promising cancer drugs would develop those drugs for children with cancer.

As we move away from chemotherapy to molecular targeted drugs, RACE, this legislation, would help provide treatments to already treatable cancers that would represent a huge, huge improvement in standard of care and improve long-term outcomes for survivors. I am sorry, Mr. Chairman that we cannot adopt the RACE for Children Act today. I along with Chairman Mike McCaul and Congressman Mullin and our staffs continue to work in a bipartisan and bicameral way to finalize language that will be consistent between the two chambers.

Mr. Walden and the Ranking Member Pallone, this bill is a good policy. Repeat -- Chairman Walden and Mr. Pallone, this bill is a good policy. It makes sense and it will help children living with cancer to have the best chance at a long and happy life. I ask that you and your staffs continue to work with me and the other sponsors to work these differences out and get this bill to the floor and to get it to the floor soon. At this time I would like to yield my remaining time to my ranking member, Mr. Pallone.

Mr. Pallone. Well, thank you, Mr. Butterfield. I want to thank you, Ms. Eshoo and Mr. Mullin for their support and tireless work on policies to support and encourage development of critical and promising treatments for children. I know there continues to be interest from these members and from stakeholders for reforms to strengthen the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act, including how we can ensure the companies that are developing promising cancer treatments are also studying these treatments in pediatric populations as well. These are policy goals that I know members of this committee and across the capitol support.

I am committed to working with our members as well as industry and other stakeholders to find a consensus on how we can best ensure that drugs are studied and labeled appropriately for use in children and I hope we can engage in a bipartisan process to reach this goal moving forward. I yield back to the gentleman from North Carolina.

Mr. Butterfield. -- words and I yield back. Unless someone else needs the time I yield back, Mr. Chairman.

The Chairman. I thank the gentleman for his work and caring on this issue and we intend to work with you going forward. Are there other members seeking recognition on the amendment? If not, does the author of the amendment wish to withdraw the amendment? The gentleman asked to withdraw his amendment. Without objection, the amendment is withdrawn.

Are there other bipartisan amendments? Are there other amendments to the legislation? Mrs. Walters, for what purpose do you seek recognition?

Mrs. Walters. Mr. Chairman, I have an amendment at the desk.

The Chairman. The clerk will report the amendment.

The Clerk. Amendment to Committee Print of H.R. 2430 offered by Mrs. Walters.

[The Amendment offered by Mrs. Walters follows:]

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

The Chairman. Without objection, further reading of the amendment is dispensed with. The gentlelady from California is recognized for 5 minutes to discuss her amendment.

Mrs. Walters. Thank you, Mr. Chairman. My amendment would help to enhance FDA's ability to implement a widely supported provision of the 21st Century Cures Act that requires FDA to classify a medical device accessory based on its own risk as opposed to classifying the accessory based on the risk imposed by its parent device.

This amendment would simply provide FDA with an operational process to implement its existing authority to independently classify an accessory device. It is important to note that this amendment does not change FDA's scientific decision making process when determining the appropriate classification for a medical device. The current process places a burden on FDA's resources which could be better utilized within the agency.

When testifying on this issue before the Health Subcommittee earlier this year, Dr. Jeff Shuren, the head of FDA's Center for Devices and Radiological Health stated, quote, the process is so burdensome that it draws away resources for other day-to-day activities. So having a streamlined process could be very helpful for the agency. It would lead to the right to reduction of regulatory burden on the manufacturers, end quote.

I offer this common sense amendment so the FDA can efficiently deploy its resources and ensure companies are not

subject to unnecessary regulatory burdens. This approach will allow for the development and delivery of even more innovative, lifesaving medical devices to patients. I urge your support and yield the balance of my time. Thank you.

The Chairman. The gentlelady yields back the balance of her time. Are there other members seeking recognition? The chairman recognizes Mr. Green. He yields to you, so we will go to Mr. Green, 5 minutes.

Mr. Green. Thank you, Mr. Chairman. And I am happy to add my voice in support for this amendment and thank Mrs. Walters for the amendment. This amendment clarifies language included in the 21st Century Cures Act relating specifically to the SOFTWARE Act provision which I championed along with my colleague Congresswoman Blackburn.

The SOFTWARE Act requires the FDA to evaluate device accessories individually rather than evaluating them as based on their parent device. However, it did not provide a procedural mechanism for the FDA to perform a premarket review of a device accessory independent of its parent device. Therefore, most devices currently on the market are subject to the same risk classification as their parent device which may be higher than is necessary for their safe and effective use. Further, new accessories that are not yet on the market will undergo FDA review would benefit from legislation and establish a procedural mechanism for the determination of their risk classification.

The only available mechanism for new accessory to utilize at this point is the de novo process which was not developed with the review of new accessories in mind. This amendment remedies these issues allowing the FDA to operationalize the intent of the 21st Century Cures Act.

Last month I had the opportunity to question Dr. Shuren when he was before the committee about the implementation of the accessories provision. He confirmed that the implementation was at issue for the FDA. I am glad the committee is being responsive to his comments, and urge my colleagues to support this amendment.

And again I want to thank us because 21st Century Cures is a great bill, but like every piece of legislation we need to go back and look at and see how we can make it better. And again I thank Mrs. Walters for doing this. And I will be glad to yield to my colleague, Congresswoman DeGette.

Ms. DeGette. Thank you. Well, as the coauthor of 21st Century Cures I, too, really appreciate this amendment and I appreciate, Mr. Green, your words about how we just always need to keep improving on the way it works. So I am delighted to support the amendment. I yield back to you.

The Chairman. The gentleman yields back the balance of his time. Are there other members seeking recognition on the Walters amendment? Seeing none, the question now becomes for the committee on approval of the amendment.

Those in favor will say aye.

Those opposed, nay.

The ayes appear to have it. The ayes have it and the amendment is adopted.

Are there other amendments to come before the committee? Ms. Schakowsky, for what purpose do you seek recognition?

Ms. Schakowsky. I have an amendment at the desk, Schakowsky Amendment Number 1.

The Chairman. The clerk will report the amendment.

The Clerk. Which amendment? There are two number 1s.

Ms. Schakowsky. Number 1.

The Clerk. Oh, this one. Amendment to Committee Print of H.R. 2430 offered by Ms. Schakowsky.

[The Amendment offered by Ms. Schakowsky follows:]

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

The Chairman. Without objection, further reading of the amendment is dispensed with. The gentlelady from Illinois is recognized to speak on her amendment for 5 minutes.

Ms. Schakowsky. Thank you, Mr. Chairman. My amendment would create a voluntary pilot project to evaluate postmarket safety of medical devices by collecting surveillance data with a focus on high risk devices and other devices that are critical to the public health.

There is no question that we need to improve the postmarket safety of medical devices. Millions of Americans rely on medical devices to maintain their health and well-being. For example, diabetics rely on insulin pumps to control their diabetes; patients with heart disease rely on internal defibrillators to regulate their heart function.

Older Americans who have had a knee or hip replacement rely on those replacement devices for their everyday functioning. And yet there is little done to evaluate those devices for long-term safety and efficacy once they are on the market.

Over the past few months I have become increasingly concerned with the safety of two internal defibrillators manufactured by St. Jude Medical which was recently acquired by Abbott. The issue first came to my attention when a staff member of mine was forced to undergo surgery to have her St. Jude defibrillator replaced because her device no longer worked properly. Last October, FDA released a safety communication regarding battery depletion for

two of St. Jude's devices.

At the time, two patients had died as a result of this faulty device and another 47 had reported dizziness or fainting. The rapid draining of a battery can happen in a manner of days leaving patients with little time to rectify this issue before facing possibly grave concerns. Then in January, FDA released another communication detailing a possible cybersecurity threat from these same devices manufactured by St. Jude Medical.

Finally, in April, the FDA sent St. Jude Medical a warning letter detailing ongoing safety issues and the lack of action taken by St. Jude Medical to correct these problems. Specifically, the FDA maintains that St. Jude Medical sold defibrillators that it knew to be faulty, for years, and downplayed the seriousness of battery failure in its defibrillators. In addition, the FDA confirmed that St. Jude Medical failed to tell their own management and advisory board after patients died due to battery failure.

The devastating consequences of faulty medical devices like defibrillators manufactured by St. Jude, clearly illustrates the need for better postmarket oversight. We need to work to better ensure that devices are safe for use for years after their approval. Many of these devices, especially high risk devices like defibrillators and hip replacements, are expected to last for many years, if not the remainder of a patient's life. I am very concerned because my staff person who is fragile had one of

these defibrillators. We need to have better information on how those devices are performing years after they are implanted in a patient and need to make it clear to manufacturers that they will be held accountable when their devices put patients at risk.

And that is why this amendment is so important. This pilot project is the first step to improving our postmarket surveillance of medical devices and better understanding the long-term functioning and risk of those devices. I urge my colleagues to support this amendment and I thank you and I yield back.

The Chairman. The gentlelady yields back the balance of her time. Are there other members seeking recognition on the Schakowsky Amendment Number 1? Seeing none, the question now becomes for the committee the favor of the amendment.

Those in favor will vote aye.

Those opposed, nay.

The ayes appear to have it. The ayes have it and the amendment is adopted.

Are there other amendments to come before the committee? We will call on Ms. Schakowsky again.

Ms. Schakowsky. Thank you. I have an amendment at the desk.

The Chairman. The clerk will report the amendment.

The Clerk. Amendment to H.R. 2430 offered by Ms. Schakowsky.

[The Amendment offered by Ms. Schakowsky follows:]

2498

2499 **********COMMITTEE INSERT**********

The Chairman. The further reading of the amendment is dispensed with unanimous consent. The gentlelady from Illinois is now recognized for 5 minutes to speak on this amendment.

Ms. Schakowsky. Thank you, Mr. Chairman. My amendment is very simple and I really encourage all of my colleagues on this committee to support it. It states the Congress needs to work to lower drug prices and ensure that every American can afford the prescription drugs they need. It is a sense of Congress that is all it is. There is not a family in America that has not been impacted by the rising cost of prescription drugs whether they struggle, whether are struggling to afford the prescription, had their insurance premiums increase due to rising drug costs, or seen more of their tax dollars pay for prescription drugs covered by Medicare and Medicaid.

And that is why 60 percent of Americans say that addressing the cost of prescription drugs needs to be a top priority for Congress and President Trump who has been outspoken on the need to do this. Seventy seven percent of Americans believe that the price of drugs is unreasonable and nearly 25 percent have actually skipped a dose of their medications due to the cost.

The drug pricing crisis cannot be attributed to a single bad actor or a few blockbuster drugs. A recent study done by AARP found that 97 percent of widely used brand name drugs had a price increase that exceeded inflation in 2015. U.S. prescription drugs spending reached a record high of $425 billion in 2015, with

expectations that such spending will surpass $600 billion by 2020.

Part D costs continue to increase considerably faster than the other parts of Medicare, which saw its total drug costs increase from $104 billion to $121 billion just between 2013 and 2014. In fact, every payer -- private insurance, Medicare, Medicaid -- have seen their spending on prescription drugs sharply increase in recent years.

And despite repeated calls for action from the American people, we have not been able to have a real conversation about how to solve this crisis and that is why I am offering this amendment today. It is time for this committee to do what the American people are asking for us to do and work together to find solutions to lower the price of prescription drugs.

This crisis cannot be solved by simply bringing more generics to market. We need a comprehensive solution that increases transparency, lowers prices for patients and the public insurance programs, and ensure that every American can get access to the drugs that they need. And so I am pleading with my colleagues on both sides of the aisle to say let's just have a sense of Congress amendment that says yes, we are going to work together and we are going to address the issue of high prescription drug prices. There are many solutions that we can offer but we have yet to have that conversation.

So let's listen to our constituents. Let's immediately begin working to advance policies. Anything less I think is a

dereliction of duty. So I urge my colleagues to support this amendment and I thank you and I yield back.

The Chairman. The gentlelady yields back. The chair recognizes himself for 5 minutes to speak on the gentlelady's amendment. I think everyone on this committee wants to do as much as we can to inject more price competition into our prescription drug market. I think it is important to understand what the underlying bill does on that front to help American consumers.

This legislation that we are working on today will help reduce the generic backlog at FDA which will inject more competitively priced drugs onto the market for patients. That is a good thing. The user fee agreements also include reforms to how generic drug and biosimilar applications are reviewed to help improve both the predictability and timeliness of reviews.

I also want to applaud Mr. Schrader and Mr. Bilirakis for working together on a real solution to help prevent bad actors from monopolizing the markets for off-patent drugs that dramatically increase prices. They worked for months together on a solution targeted at a real problem and came up with a creative way to use incentives and prioritize FDA resources toward reviewing applications that when approved will provide price competition in the market when none, none exists today.

I welcome other ideas like the amendment Mr. Guthrie and Mr. Griffith introduced which I believe will help advance value-based payments for prescription drugs in the private sector and

eliminate barriers to greater understanding and communication of how therapies can best work for patients. We should be open to working together on promising ideas to help lower health costs for patients. We are taking good steps today and we should look for every opportunity to do more.

Frankly, I think your resolution is fine and I believe we would be willing to accept it and I yield back the balance of my time. The chair recognizes the gentleman from New Jersey, Mr. Pallone.

Mr. Pallone. I guess given that you are willing to accept it I should quit while we are ahead.

The Chairman. Without objection.

Mr. Pallone. So I think I will simply enter my statement in support of the resolution for the record and leave it at that. Thank you, Mr. Chairman.

Mr. Green. Will the gentleman yield?

Mr. Pallone. I do. All right, sounds good.

The Chairman. Without objection.

Mr. Pallone. Anybody want my time? I will yield to Ms. Castor.

Ms. Castor. I will ask the chairman a question, and when can we schedule a hearing? The Senate Health Committee has a hearing scheduled on drug pricing.

The Chairman. Does the gentlelady want us to accept this by unanimous consent? Thank you. The chair recognizes the

gentleman from Vermont.

Mr. Welch. Thank you, I support this. And Ms. Schakowsky has been a leader on trying to get control on prescription drug prices, but as she pointed out there is one, I think, acknowledgment all of us have to make if we support this resolution. The resolution is one thing, legislation is another.

And this problem of how much we are paying for prescription drugs we all know is real. We have a lot of different points of view about how to bring it down. And I think on one side of the aisle there is a desire to get more competition in a more efficient FDA and approval process. That makes sense. How do we get it?

You know, our side I think believes that there are certain places where there has to be some governmental action to deal with what are clear abuses, like extending beyond the exclusivity period that gives a monopoly to the creator of the product. I mean we can't tolerate that. Or we had in the Oversight and Government Reform hearing, a hearing on what happened with Martin Shkreli, who was just a Wall Street pirate, identified a company that had a $15 product.

It wasn't on anybody's horizon and he made a shrewd Wall Street style move. He bought the company with borrowed money and then to pay it off he raised the price from $15 to $1,500. That is legal. That is the thing that is -- that is our responsibility because none of us approve of that. None of us would do that. But it is allowed to be done, and then if we are going to take

some action it does require 54 people in this room to be the ones that step up and do it.

And I think what Ms. Schakowsky is saying in this resolution is reminding us that this problem is real. We pass this resolution it is a good thing because we are all acknowledging it. You know, there is no difference in the suffering of a person who went from paying $15 to $1,500 whether they are in North Dakota or Vermont. It is the same pain for the same people.

And Mr. Chairman, I just join in the request that we kind of get real about this and real means that we have hearings that are scheduled. We take steps that say to Pharma, look, we appreciate what you are doing, but let's lighten up on the gas pedal here. People can't afford this situation. So yes, I am for this resolution in the spirit in which Ms. Schakowsky has offered it, but I am just imploring all of us here to accept our collective responsibility to actually do something that brings prices down or stabilizes them. I yield back.

The Chairman. The gentleman yields back. Further discussion on the amendment? The chair recognizes the gentleman from Georgia, Mr. Carter.

Mr. Carter. Thank you, Mr. Chairman. I just want to add my thanks to the gentlelady for offering this. This is certainly something that I have a strong interest in, currently the only pharmacist serving in Congress and perhaps the only one who has really witnessed firsthand the dilemma that many patients face

when they are trying to get prescription medications and the obstacles that are there when the accessibility, because of price, is a problem.

And I want to commit that this is something that is very important and that I intend to be working on. This is more than just a formality here. We will continue to press. I have met with the chairman. I met with Chairman Burgess and expressed to them all my desire to continue to work on this and to have legitimate results. And again want to thank the lady and I look forward to supporting this amendment and I yield back.

The Chairman. Thank you. The gentleman yields back the balance of his time. The chair recognizes the gentleman from Iowa. We would like to move on to the other amendments at some point for other members, but you are recognized for 5 minutes.

Mr. Loebsack. Thank you, Mr. Walden. Drug prices are particularly important in the history in the state of Iowa. Whether it is working families or seniors, folks across my state and really throughout America, as Mr. Welch said, are struggling to keep up with the rising prices of prescription drugs. Many Americans rely on their prescribed medications for their health and well-being and that is why it is imperative that these be affordable. I think we can all agree on that.

And I have seen firsthand the heavy burden, the high cost of prescription drugs can be for many families. Each weekend when I am home one of the most common things I hear from folks is how

expensive their prescriptions are and how they worry about being able to afford them. And that is why I, and I think all of our colleagues here today, remain fully committed to reducing the price of prescription drugs because no family should have to choose between putting food on the table and paying for their medication.

And I am always happy to work with Mr. Carter on these kinds of issues too. We have worked on a bipartisan basis to make sure that there is a transparency when it comes to these issues, too, for pharmacists. And so I do support Ms. Schakowsky's amendment and I yield back.

The Chairman. The gentleman yields back. All right, the gentleman is recognized for -- turn on your mike there and I will recognize you, the gentleman from Vermont.

Mr. Welch. I have an article from the Burlington Free Press about skyrocketing drugs hitting home with a $89,000 price tag.

The Chairman. Without objection, entered into the record.

[The information follows:]

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

The Chairman. The chair recognizes Mr. Tonko.

Mr. Tonko. Thank you, Mr. Chair. And quickly, I support the Schakowsky amendment and I thank her for her tireless leadership on this important issue. The time for talk is over and the time for action is now. Every day I hear stories from constituents, as I am certain most of us do, about the outrageous prices that constituents are paying for medications to keep them healthy and alive.

Janice from Albany wrote to me last year about the drugs she takes to manage her mental illness. Her monthly cost went from $9 to $342. That is not right. Irene from Hagerman has seen her monthly prescription jump from $35 to $250. That is not right. Mario, a retiree from Fort Johnson in my district, is paying $900 for a 3-month supply of his reflux medication. That is not right. And Regina from Rexford saw the monthly cost of her rheumatoid arthritis medicine jump from $2,800 to $3,700 in just 1 year. That is just plain wrong.

Despite these stories, these cries for help from our constituents, what has Congress done? All talk no action. President Trump made lowering prescription drug prices a centerpiece of his campaign. What has he done since then? All talk no action. Today we finally have a chance to take action. America leads the world in this development on new and innovative lifesaving cures and that is something we should be proud of and continue to cultivate. But we should be ashamed of the fact that

oftentimes our own citizens don't have effective access to these innovative treatments.

I fully understand that drug pricing is a complicated issue that we don't want to stifle American innovation that will help to create the next generation of lifesaving treatments. But it is not that complicated to believe that in the richest nation on earth no one should have to go bankrupt to obtain a lifesaving medicine.

A recent poll found that both Republican and Democratic voters agree in making this the number one priority for Congress. Let's make it happen for the American people. This situation must be fixed. We can take a good first step and show that we understand the importance of the issue and show it through accepting this amendment as the chairman just indicated. I urge my colleagues to support this common sense amendment. Let's move forward, and with that I yield back, Mr. Chair.

The Chairman. The gentleman yields back. Are there other members seeking recognition? Are we prepared to vote?

All those in favor of adopting the Schakowsky amendment will say aye.

Those opposed, nay.

The ayes have it, the amendment is adopted.

I believe the chair now looks for other amendments. The gentleman from West Virginia, for what purpose do you seek recognition?

Mr. McKinley. I have an amendment at the desk, please.

The Chairman. The clerk will report the amendment.

The Clerk. Amendment to the Committee Print of H.R. 2430 offered by Mr. McKinley.

[The Amendment offered by Mr. McKinley follows:]

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

The Chairman. The gentleman is recognized for 5 minutes to speak on his amendment.

Mr. McKinley. Thank you, Mr. Chairman. The loss of hearing is a symptom of a problem, but stereotypically society will say get a hearing aid. That is, get a hearing aid. But even the Hearing Loss Association of America says that there could be far more serious problems that as Congressman Kennedy said if left untreated.

You got issues like the malformation of the inner ear, fluid in the middle ear, allergies, the Eustachian tube, perforated eardrum, benign tumors, impacted earwax, infection in the ear canal, foreign bodies, otosclerosis, items that only a specialist or, excuse me, someone trained in hearing loss may be able to detect. So the Hippocratic Oath says do no harm. Do no harm.

By putting in a hearing aid you are ignoring all those issues that could lead to more profound loss. And I am certainly one that is the example of that myself on that because I wound up ignoring some of the symptoms and I wound up losing my hearing entirely. I am profoundly deaf and if it weren't for a cochlear implant I couldn't hear a thing.

I think that what we are trying to encourage by this legislation, by this amendment is to encourage individuals with hearing aids or that have hearing impairments, check with a doctor or check with a specialist to find out what that is, because even with a hearing aid you could actually cause more damage to yourself

by having overamplification on your inner ear that you can cause damage to your eardrum. Let's be careful about this.

So what we are trying to do in this legislation is to encourage people to, one, see a specialist to find out what is causing your hearing -- don't just do that stereotypical just put a hearing aid in and turn it up. That doesn't address the real problem. That is an un-treatment. With the secondly is do a self-assessment. I did. While we were sitting here I did a self-assessment that was provided by the Better Hearing Institute. That is worth talking about.

Just do a self-assessment. That is the alternative as well. And the self-assessment for moderate loss it says for a person with -- if I had had the losses I am referring to it says a hearing test is highly recommended. You are experiencing difficult hearing in important listening situations and may need hearing aids. That is all we are talking about with this amendment. Have someone else verify it. Don't take the simplistic stereotypical answer just get a hearing aid. In so doing you are ignoring a symptom, something else that may be more sinister lurking inside your hearing.

That is what happened to me. I am deaf now. I ignored it. I shouldn't have done that. And it wasn't until I went to the Mayo Clinic when they said we could have saved your hearing if you had just taken calcium gluconate and sodium fluoride. I didn't know that. I put a hearing aid in. Shame on me, this is

my fault. I am trying to prevent other people from losing their hearing as a result of this. Get your ears checked by a professional.

That is what this legislation, this amendment is trying to do. I support the idea of the OTC. I think it is a great idea to be able to do that but I think it ought to be coupled with getting your hearing checked. Find out why. Don't just say put a hearing aid in, because you actually could be doing more damage to yourself by putting in something with a 70 decibel increase into someone that only has a 10 decibel loss. Just be careful about this.

So we are looking for ways to get this encouragement. Find a way for the FDA to encourage people to get their ears, people to get their ears checked. Find out what is causing the loss. Mr. Chairman.

The Chairman. Will the gentleman yield? I would like to ask the gentleman, first of all, thank you for telling your story. I think it will help Americans figure out they have a real problem they should get more professional attention to.

I would like to ask the gentleman from West Virginia to withdraw his amendment and between now and when the bill reaches the floor that we might work together to include report language to encourage the FDA to ensure that licensed hearing professionals be consulted in the rulemaking process to establish this new category of over-the-counter hearing aids any requirements that are included. Will the gentleman be willing to work with us on

that?

Mr. McKinley. I am certainly willing to work with you. I am trying to understand the mechanics. Could that end up being in the rule that there is perhaps on the device, on the box of the device or on however it is sold there might be a warning on there to have your hearing checked?

The Chairman. That would be an FDA decision, but I believe that would be the potential outcome. I don't want to --

Mr. McKinley. I know.

The Chairman. -- say what the FDA will or won't do. But I would think in working with hearing professionals that this would be part of their rulemaking process and it would seem only logical that such a disclaimer would appear on the device or on the box. So there would be an educational component to this, which is what I think you seek.

Mr. McKinley. Yes. I want, one, to encourage people to have their hearing checked.

The Chairman. Right.

Mr. McKinley. Find out what is causing your loss, not just simply getting a hearing aid. And secondly, doing, and it may very well be before you go out and acquire an OTC that you have a self-assessment somehow to find out whether or not this is really what the problem is.

The Chairman. And the interesting part is, it seems to me that if you were in search of an over-the-counter device and it

had this label it might actually cause you to go do exactly what you are after, which is to consult a professional where otherwise you might not even do that.

Mr. McKinley. I hope and with your encouragement is that I am trying to visualize from 30,000 feet down to where you and I have to be at this point --

The Chairman. Right.

Mr. McKinley. -- that it may be printed on the box or something may be through the rule there is some kind of encouragement strongly encouraging seeing a hearing professional.

The Chairman. And let me suggest that you know, we will have an opportunity at some point to speak with the FDA and the FDA commissioner and I would be happy to arrange such a meeting with you and him to have this discussion, because he should hear your own life story as it --

Mr. McKinley. Not so much.

The Chairman. No, no. But you --

Mr. McKinley. Not so much even a life story. There is so many people that have written me --

The Chairman. -- made it clear.

Mr. McKinley. -- and encouraged me to continue to fight this on because they are the ones that are dealing with people that have ignored their problem for too long and they are seeing this.

The Chairman. Exactly.

Mr. McKinley. So I don't need to list them all, but I have page after page after page here of groups that have said they want this amendment.

The Chairman. Would you mind putting those in the record?

Mr. McKinley. I certainly can.

The Chairman. Without objection, we will put those in the record for everyone to see.

[The information follows:]

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

Mr. McKinley. And as long as I have a strong commitment that there could very well result in something being printed on the literature, something, some recommendation, then I will withdraw the amendment.

The Chairman. I would yield to -- I think that is correct. Before I yield back I want to yield to the gentlelady from Tennessee for just a comment.

Mrs. Blackburn. I thank the chairman for yielding and I thank Congressman McKinley for his passion on this issue and for the conversations that we have been able to have about this.

As we had talked earlier prior to this markup, packaging and labeling on packaging is a very effective way to participate in consumer education. And with other over-the-counter components, whether it deals with orthopedics or vision or different things, you will see educational information on the packaging and it is a point of purchase approach to consumer education for several past decades. It has proven to be successful.

And I appreciate Mr. McKinley raising the issue and working with us between now and the time we go to the floor to look at a way that we can work with the FDA and encourage that educational component onto the packaging for these devices. And I yield back to the chairman.

The Chairman. Appreciate it. Mr. Rush?

Mr. Rush. Mr. Chairman, I want to commend my good friend from West Virginia, Mr. McKinley, for having the courage to share

with us his personal story. And I for one was very moved by it and I can see that there is a possibility or there is a likelihood that there is millions of Americans who are suffering from the same fate. As you were speaking I was even reconsidering my own hearing issue that I have just ignored, and I certainly won't ignore it anymore as a result of hearing my friend, Mr. McKinley's comments.

But Mr. Chairman, I also understand what we are attempting to do here in terms of the markup and trying to get a bill out, but I certainly would not want us to lower the real positive mark, standard that he set, all right. Let us not just miss the mark and let us not just simply for trying to get the bill out disregard what he is saying and what he said.

And I am not sure what the solution is, I just want us to maintain the standard that my friend Mr. McKinley established for this markup and for this committee. It is a high standard and I just --

Mr. Doyle. Will the gentleman yield?

Mr. Rush. I certainly will.

Mr. Doyle. Thank you, Mr. Rush. I just want to encourage Mr. McKinley to stay with this. My brother is a speech pathologist and audiologist and we have talked about this issue and he is very concerned that with these sales that a lot of people just are not going to get the advice and the examinations they need prior to making a decision. And putting information on a

package, people either don't read it or they don't understand it when they read it.

I think it is very important that, you know, I am fine with this idea of having more access to hearing aids over the counter, but it should be accompanied with an examination by a professional. And Mr. McKinley, I support what you are doing and I hope you stick with it and work with the chair that we get language that makes sense and protects our constituents. So I want to thank you for that and I will yield back to Mr. Rush.

Mr. Kennedy. Will the gentleman yield? Thank you. I will be very brief. I want to recognize Mr. McKinley's comments and very personal testimony and also acknowledge the fact that over the course of the past several weeks he has brought up some of the concerns that he has had about, I don't believe underlying, the intent underlying this legislation but the concerns that he has, given his own very personal experience with them and I salute him for that.

I look forward to taking the chairman's suggestion here and seeing what we can do going forward with this. I would point the committee to under the regulations to establish category of the actual text itself under requirements that talks about the regulations contemplated in the legislation that in large part, due to Mr. McKinley's advocacy along with some others, there has been language added to this version of this legislation that asks for additional language to be put on the labeling that has

advertisements, quote, to consult promptly with a licensed physician.

So there are some of those concerns, recognizing those concerns and the ones, sir, that you have brought up, part of that concern is recognized. I certainly think we can do more between now and the time that hopefully this gets to the floor and in that rulemaking process, but I did want to point out that part of those concerns that you have raised have been recognized and put into this final version of the text between where it came from initially and where it is today and I wanted to acknowledge that. With that I yield back.

Mr. Upton. Mr. Chairman.

The Chairman. And the gentleman from Illinois yields back, right?

Mr. Rush. I yield back.

The Chairman. I recognize the gentleman from Michigan.

Mr. Upton. I just strike the last word and I don't intend to use very much time. I appreciate the gentleman's work. I would support his amendment. I think this is a good place for us to be. We all want to make sure that the consumer is protected and has the best education that they possibly can get.

I appreciate Chair Blackburn's urging as well, and I look forward to working with all parties to make sure that that process is followed and understand where the chairman is and look forward to working with the parties to get it done. Thank you, I yield

back.

The Chairman. I appreciate all the members' concern about this and certainly Mr. McKinley's and we look forward to working with you and others on the committee to make sure we get this report language correct. So does the gentleman seek to withdraw his amendment?

Mr. McKinley. Mr. Chairman, I think I know the temperament what is about to happen, so I may be so like I say, I may be deaf but I can count. And if this is the better part of valor to work it out this way --

The Chairman. Victory always is.

Mr. McKinley. I am looking for something to hang onto so that we can continue this fight.

The Chairman. Correct.

Mr. McKinley. So I will withdraw with that understanding that you and I have that we are going to try to get some kind of, are going to encourage the testing to be part of this.

The Chairman. We will work together to find that solution based on the language I read to you here. All right, so the gentleman withdraws his amendment. Are there further amendments to the bill? The gentleman from Vermont, for what purpose do you seek recognition?

Mr. Welch. I have an amendment at the desk.

The Chairman. The clerk will report the amendment.

The Clerk. Amendment to Committee Print of H.R. 2430

offered by Mr. Welch of Vermont.

[The Amendment offered by Mr. Welch follows:]

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

The Chairman. Without further objection, the further reading of the amendment is dispensed with. The gentleman from Vermont is recognized for 5 minutes to speak on his amendment.

Mr. Welch. Thank you very much. This amendment would allow the importation of drugs from Canada. I want to tell you the origin of this. We talked a little bit earlier about the incredibly high price of prescription drugs in our country, much higher than any other part of the world.

And everybody has their story, but one that hit home was in Burlington in a report by the Burlington Free Press. An American pharmaceutical company was planning to charge $89,000 for a drug used to treat muscular dystrophy that was available overseas in England for $1,000, and the price increase announcement was really a hammer to the muscular dystrophy community.

Joanne Wechsler's son Adam started having some symptoms when he was a toddler, but they were dealing with this by being able to get the prescription drug at an affordable cost. And all of us have empathy for a family that finds that what they were paying $1,000 for suddenly is going to go to $89,000. That is real. This question of importing prescription drugs has been around for a number of years. It is resisted for a number of reasons, some of the concerns very valid that I will try to address.

But first of all, I want to say something about importation. It is already happening. Today prescription drug companies in the United States import 80 percent of the active pharmaceutical

ingredients and 40 percent of finished prescription drugs from other countries. Also, our constituents who are desperate to try to be able to afford that drug that they need for the person they love, 8 percent of them, 19 million people are already doing this. They are buying prescription drugs sometimes on the internet. That is not really particularly safe.

But importation is already happening. My amendment would make legal importation from Canada but under strict circumstances. The only drugs that could be imported would be ones that were manufactured in an FDA-approved facility. That manufactured product would have to go to a Health and Human Services-approved distributor and then would have to be imported directly from that distributor to the United States either by a pharmacy or by an individual user.

So we can talk as I am sure we will about safety, and I have total respect for the concerns of my colleagues about safety, but I think we have addressed those in this bill. No narcotics would be allowed to be imported, so that we keep that at bay. We have talked a lot about prescription drugs and we just passed the Schakowsky amendment.

But I have got to tell you is something you know that price increases just have been unrelenting. And I have been a beneficiary, my family has, of the good stuff that Pharma does, but when these prices just never stop and the justification from Pharma for these price increases is that they are doing good --

and they are doing good -- that becomes an excuse for doing bad, killing folks with these price increases. And the question for our committee is whether we are going to do anything about it.

The question for Pharma, the pharmaceutical industry is whether you are going to be able to have some restraint. Restraint, because in effect there is this system that really sets up these monopolies here and monopolies there. It starts with something we all support and that is the exclusivity period, but then things start running awry because companies that have that exclusivity period and have benefited by it abuse it and they keep the generic off the market both in name brand and biosimilars. That is a problem. We have companies that then make these minor little adjustments in their product and that becomes the basis to say it is a whole new drug and we extend the exclusivity period again. And this just can't go on.

You know, I had the opportunity to meet with President Trump with Elijah Cummings who has been a longtime champion, and I have got to tell you the President got it. He was talking about these ripoff prices and that there is not a justification even as we admire what Pharma is doing and the prescription drugs that they are providing to help our folks be healthy and live with really bad and dangerous conditions like this young man and his mom. And he made it clear in his campaign and in that conversation with us, the drug importation in his view could be done safely.

And another question for us is the U.S. is the center of

innovation when it comes to pharmacy innovations, but is it really fair for us to have a system where our citizens, our taxpayers, are the only ones that have to pay for the cost of innovation and then that benefit is exported to all these countries that have much lower prices than we do, or should that cost of innovation have to be shared?

The Chairman. The gentleman is about a minute over, so.

Mr. Welch. I am sorry. I appreciate your indulgence. So I offer this amendment and look forward to our debate on it. Thank you.

The Chairman. I thank the gentleman. Are there other members seeking recognition on the amendment? The gentleman from Georgia, our pharmacist, Mr. Carter.

Mr. Carter. Thank you, Mr. Chairman. And first of all, let me thank Representative Welch for his attention to this matter. There is no question that this is a problem. But respectfully, I have to say that I will have to oppose this amendment and I would urge my colleagues to oppose the amendment as well.

As you know, for over 30 years I have practiced pharmacy and I have witnessed this firsthand. I have had patients who have gotten medication through the internet, through the mail from other countries who have brought it to me and I cannot in my professional opinion really make sure and give them the type of assurance that that is the medication that it is purported to be. That is something that we cannot do. This is a very slippery slope

and certainly the job that the FDA does in making sure that we have safe and effective drugs is to be complimented and is to be applauded. It is a very important part of what they do.

But I want to make sure that we understand what we are doing today. This underlying bill, it does help. It does help with more competition. It does help to make sure that we are going to have lower costs by having more competition, by making sure that we streamline the process without compromising any of the safety that we need to have in there. Every FDA commissioner both Democrat and Republican has opposed the idea of drug importation. Let me read the letter that they have sent on this issue.

"We urge Congress and the many others concerned about the cost of drugs to deal directly with the issues driving the costs of medicines and not place false hope in measures that will place patients who need treatment at risk and jeopardize public health."

This is certainly something that we need to be aware of. There are ways that we can lower costs of medications and we are going to be working on that. As I mentioned earlier, I have the commitment from both Chairman Walden as well as Chairman Burgess that we are going to be addressing this. I just simply cannot in my right mind support this amendment.

Whereas, again I appreciate the efforts of the gentleman to bring about for lower prices, this is something that I don't think is the right route for us to be taking. We need to deal with it internally here in our country to make sure that the medications

that people are getting are indeed exactly what they are supposed to be and what they think they are. So I thank the gentleman, but again I want to say that I will be opposing this amendment and I urge my colleagues to oppose it as well. And I yield back.

Mr. Upton. [Presiding.] The gentleman yields back. The chair will recognize the ranking member of the full committee, Mr. Pallone, for 5 minutes.

Mr. Pallone. Thank you, Mr. Chairman. I want to speak in support of the amendment offered by Congressman Welch. We have all heard from patients and families and increasingly from our healthcare entities about how the skyrocketing costs of prescription drugs is impacting their bottom lines. From the families who can no longer afford to buy their son or daughter's EpiPen to the state Medicaid program trying to figure out how to pay for the next Sovaldi, real people are making hard choices about how to compensate for these rising costs.

I have said on more than one occasion that I am ready to work with my colleagues in this committee and in the House on a bipartisan basis to find solutions to help make the cost of prescription drugs more affordable. All the improvements and efficiencies in the drug review process that we are considering here today will mean nothing if patients and families can't afford the latest innovations in medical treatments.

I know that many stakeholders and many of my colleagues in Congress believe that reimporting lower cost prescription drugs

may be one way to address the very real crisis in front of us. Under current law, importation is permitted if FDA can determine that importation would pose no additional risk to public health and safety and if importation would generate significant cost savings to the American consumer. While no certification has been made to date, I am hopeful that this administration will take seriously the President's pledge to look at ways we can bring drug costs down for American families.

I have continuously said that I will support policies that will provide relief to families, and this reimportation policy holds potential to meet this goal so I would urge support of the Welch amendment. I yield back.

Mr. Upton. The gentleman yields back. Are there other members wishing to speak on the amendment? The gentleman from Pennsylvania, Mr. Doyle, is recognized for 5 minutes.

Mr. Doyle. Thank you, Mr. Chairman. I appreciate what Mr. Welch is trying to do here today. I don't know that this amendment will necessarily make a huge difference, but what Peter is talking about is right. Drug prices in this country are higher than they are anywhere else in the world. Why is it that we are the only country in the world that doesn't negotiate drug prices for our citizens? We do it in VA and everybody seems to appreciate the fact that our veterans are able to get their drugs at a much better price because we have negotiated with the drug companies on that pricing. We tried to do that with Medicare Part D. We lost that

by one vote and that vote took about 4 hours to get the last person down the middle of the aisle to pass it.

It seems to me that the United States, when you think about all of our seniors on Medicare and the need for some of these drugs, we would have the best bargaining situation of any country in the world, yet our citizens pay $6 billion just this year in pharmaceutical advertising. Our citizens pay for all the research that is done to bring new drugs to the market while every other country in the world is getting these same drugs made by the same companies at a price substantially lower that what our citizens are paying.

Peter has pointed out that in Canada they can make a drug in Canada in an FDA-approved facility under the license of HHS and still mark it up and sell it in the United States cheaper than someone can buy the drug here in the United States, to give you an idea of what the spread must be between what people in countries like Canada and the rest of the world are paying. And Americans have to split their pills in half or in four pieces or not take their medicine in the way it is being prescribed or give something else up so they can afford their medicines, because this Congress hasn't had the courage to sit down and negotiate drug prices for our citizens with the pharmaceutical industry that made the top five companies last year made a combined profit of $54 billion. This has got to stop. This needs to change.

Now Peter's amendment isn't going to change that. What

changes that is us sitting down and having a frank bipartisan discussion on behalf of the constituents we all represent, Democrats and Republicans and Independents alike, of what we are going to do as a Congress to get a handle on these rising drug costs. That is what we ultimately need to do.

What Peter is doing here today is making a statement bringing awareness to this issue. And while his amendment may not solve our problems today, don't kid yourself that the American people don't want us to do something on their behalf when it comes to drug prices.

So I am going to support Peter's amendment today because I think we need a wake-up call in this country and in this Congress that it is time to sit down bipartisan and deal with the price of drugs in this country and put us in line with every other country in the world who has access to our manufacturers, our products at a price way lower than what our citizens are paying for. That time has come and there is no reason we shouldn't be able to do that. And I yield back.

Mr. Upton. The gentleman yields back. The gentlelady from Illinois, Ms. Schakowsky, is recognized for 5 minutes.

Ms. Schakowsky. Thank you. I move to strike the last word. I support Congressman Welch's amendment because it certainly is past time for us to take action to make drug prices more affordable for all Americans. There is no reason why patients are paying double or more for certain prescription drugs compared to our

neighbors in Canada. For example, the price of an EpiPen is $292 in Canada compared to $638 in the United States; Celebrex costs over a thousand, $1,100, actually, in the United States while Canadian patients pay $257.

The price of Abilify in the United States $2,800, while in Canada it is $546. The same drug. In fact, in 2014, U.S. consumers spent 40 percent more per person on prescription drugs compared to Canadians. Moreover, I believe that reimportation can be done safely. According to the FDA, 80 percent of active pharmaceutical ingredients and 40 percent of finished prescriptions drugs are imported from other countries. Given the fact that Republicans on this committee refuse to even admit -- well, no, I guess we just passed a resolution -- are admitting that we have a drug pricing problem, and I am so grateful for that, then we need to begin to do something right now.

This is an opportunity. Importation will not solve all the problems in our prescription drug market, but we still need to increase transparency, require Medicare negotiation and anti-competitive behavior, reduce exclusivity for high cost drugs like biologics. However, this amendment is an important step forward toward lowering drug prices for Americans. And I thank you and yield back.

Mr. Upton. The gentlelady yields back. Are there other members wishing to speak on the amendment? The gentleman from New Mexico is recognized.

Mr. Lujan. Thank you. And Mr. Chairman, before we vote on the amendment there are a few questions that I have that I just wanted to make sure that I got on the record and that I am hoping we can get some responses to as we have this debate and conversation.

There is no question that we see a concern with high prescription drug prices in the United States. And I appreciate all of our colleagues supporting the resolution that was authored by Ms. Schakowsky recognizing the importance of what we must commit to on this committee and in this Congress, not only to have committee hearings to author legislation that will allow us to be able to get to that lower price for the American people.

And so if the author of the legislation might be open to entertaining a colloquy with me, one of the questions that I have is how exactly will allowing U.S.-based wholesale distributors to purchase bulk orders of Canadian drugs guarantee that savings are passed on to consumers in the United States? And I would yield to Mr. Welch just to determine how we might be able to see those savings for the American people if this language would become law.

Mr. Welch. Well, two things. Number one, you have got Mr. Carter here and he might be able to speak to that. But I bet you get a pharmacist who is able to get the product at a much cheaper cost to the pharmacist. The pharmacists I know that have been tremendous help to my family, they are into the health benefit and they are concerned about the cost, so I have lot of confidence

that somebody like Mr. Carter if he had to pay 50 percent less would pass on a significant part of that to his consumer.

But the bottom line here is that in a marketplace if the cost of product is $5 you are going to charge one price, if the cost of product is $50 you are going to charge a lot more. And I can't answer that other than by saying that I think there is a market force and I also think that there is some decency particularly among, especially among our pharmacists who, in my view, have been outstanding players in this whole episode.

Mr. Lujan. I thank Mr. Welch. And the reason that I asked that question is while I would hope that savings would be passed on to the consumer, one of the concerns that I have is what we have seen and what we are continuing to learn more and more about with pharmacy benefit managers who negotiate prices with pharmaceutical manufacturers, cost savings it does not appear are always passed on to consumers.

So while we are seeing negotiated prices that are lower, I want to know why those aren't being passed on to the consumers. And I will yield in a second, but that is something that I hope this committee can take up with as well is the concerns that exist broadly. And I think across the aisle in both chambers, and I hope in the White House with this treatment as well, so that we don't see that, you know, someone would reap and benefit from larger profit margins rather than passing the savings on to consumers.

The other thing that I just wanted to point out is the Pew Charitable Trusts had authored a letter of talking about some of the concerns that I have from a safety perspective. And the Affordable and Safe Prescription Drugs Importation Act attempts to integrate importation provisions with what we call track and trace, where there is -- but the concern from Pew is that there was significant gaps that still would remain that would compromise the security of the U.S. supply chain.

While in many circumstances foreign sellers would be required to purchase from FDA-registered facilities, it is unclear how that requirement would be enforceable particularly given the potential of profit for entities that purchase from illegal sources and sell them to the U.S. market. Even if it were, a product would be sold in the U.S. system without the product identifiers necessary to allow a fully electronic and interoperable drug security system.

So I know that I count on a lot of research that is done with Pew and the charitable trust there, concerns that still exist with online safety from an organization called the Alliance for Safe Online Pharmacies as well. And so while I will support the gentleman's amendment, I am hoping that there is some agreement here that with the areas that still need attention that there is work to be able to improve that language to make sure we address each and every one of these concerns as well. Mr. Welch?

Mr. Welch. Well, first of all, Mr. Lujan, I really

appreciate that because safety can't be compromised, and you have been a big advocate for guaranteeing patient safety. And I tried my best to take into account those very legitimate concerns.

Bottom line here, under the legislation the product has to be manufactured in an FDA-approved facility. It has to be sent directly to an HHS-approved dispensary. The HHS secretary is empowered to follow through with any additional provisions including bar codes to guarantee that track and trace benefit that we have here in the U.S.

But I would certainly be willing to work with the gentleman to try to give him full confidence that any prescription that was purchased in this manner was safe.

Mr. Upton. The gentleman's time has expired. The chair would recognize the gentleman from Illinois, Mr. Shimkus, for 5 minutes.

Mr. Shimkus. Thank you, Mr. Chairman. This is an important part of the debate and the discussion because we have in our possession a letter from former FDA commissioners, Robert Califf, medical doctor; Margaret Hamburg, medical doctor; Mark McClellan, medical doctor, Ph.D.; Andrew von Eschenbach, medical doctor, and their bullet points basically say this process is serious risk to patients and consumers.

And I think our pharmacist Congressman Carter kind of mentioned that. Drugs purchased from foreign countries may be substandard, unsafe, adulterated, or fake. The FDA lacks the

resources needed to oversee a major importation program. The global drug supply system will limit improvements and access. And their last bullet point in this letter is, any improved access and cost savings resulting from importation may likely be minimal.

Now that is just from former FDA commissioners. We believe in markets and competition. We don't believe in government price controls or rationing. Part D, which was mentioned, is a great success. It is 40 percent under what was projected it to be because of allowing insurance competition and seniors to choose.

So that is, we believe, is a very successful model and provided seniors with access to prescription drugs that they never had before. And a lot of us, there is a lot who weren't here then, but a lot of us up on the top dais were here for those fights and those battles and some of these arguments were made back then.

I just want to make sure that we highlight what we are doing in this bill again because this, you know, we are going to get wrapped up in this debate and it is going to get, this is one of the few things that we are not going to agree upon. It shouldn't derail the movement of a very important bill that moves forward that there is a lot of consensus on. And I know it is not intent to derail the bill, but I do know it is an attempt to have this debate, which is, this is like the third iteration in my career that this debate has been issued.

We want to inject more competition into our prescription drug market, we believe this bill does that. We do it by the reduction

in the generic backlog at FDA to inject more competition, part of this bill; the user fee agreements also include reforms to how generic drugs and biosimilar applications are reviewed to help improve both predictability and timeliness, and we have had a great debate and some amendments on that.

Of course Mr. Schrader and Mr. Bilirakis addressing bad actors, that is a positive step. And I think to come sometime today, we will hear from Mr. Guthrie and Mr. Griffin on the value-based payment debate. I am not sure where that is going to go, but we believe that -- we understand where we are politically and why we are at this point of time, but this is a great step forward in addressing these concerns and I just don't want it to get so derailed by the emotion of the time to have us forget the good things that are going on here. And I thank the colleague and I yield back my time.

The Chairman. Are there other members seeking recognition? Seeing none -- oh, I am sorry. The gentleman from California is certainly recognized for 5 minutes to speak on the matter.

Mr. Peters. Thank you, Mr. Chairman. I will yield to the gentleman from New Mexico, Mr. Lujan.

Mr. Lujan. Thank you, Mr. Peters. And I would like to thank my colleague from Illinois, Mr. Shimkus, for citing some of the concerns from the former FDA commissioners as well. That was one of the aspects I was going to bring up, so thank you for that Mr. Shimkus.

The other thought that I guess I just wanted to share with our colleagues is, you know, with concerns associated to additional importation with opioids specifically, and I appreciate that there is a clause in the language that does not allow for controlled substances to be imported. But there was a response by the former FBI director, Louis Freeh, who said that permitting prescription drug importation would lead to an increased flow of counterfeit and other potentially dangerous products across the U.S. borders and worsen the opioid crisis.

That is something that any time I hear that there is anything that could impact the opioid crisis that we have in the United States, those of you that I have had a chance to visit with know the concerns that I have in New Mexico as well. We have generational problems. I have had tough conversations where I have sat with three generations around a dinner table that all use. And this is a problem that we know that is continuing to grow across the country. And so I just again as we are looking at the language I want to make sure that we are tightening everything that we can in those spaces as well.

And then the last thing that I would say is while we work as a committee to make sure that we are lowering prescription drug prices that I guess my observation is that as we look at Canada that their drug prices aren't cheaper because of lax laws, if you will, their drugs are cheaper because they allow drug price negotiation through the entire healthcare system. And so if

indeed we are going to be able to move something significantly on behalf of the American people, I believe that is the realm that it would be.

And there would be a disagreement, I get that. I understand that. But that would be the point that would allow for zeroing in on the costs while maintaining the pure safety of what we have been able to put together in the United States, protect the integrity of the supply chain and make sure that we don't have any counterfeits that are moving through in that regard again.

So Mr. Chairman, it was important for me to be able to get that onto the record and share my thoughts and concerns as we always work to improve language and legislation.

Mr. Shimkus. Would the gentleman yield real quick?

Mr. Lujan. Is Mr. Peters' time up?

Mr. Shimkus. Oh. Will the gentleman yield?

Mr. Peters. I will yield, yes.

Mr. Shimkus. I just want to ask permission to submit the letter from the FDA commissioners into the record.

The Chairman. Without objection.

[The information follows:]

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

Mr. Doyle. Will the gentleman yield?

Mr. Peters. Yes.

Mr. Doyle. Thank you, Mr. Peters. I just want to make the observation I agree with Mr. Lujan that the answer here is to negotiate drug prices. And my good friend Mr. Shimkus mentions Medicare Part D. A lot of us were here for that debate. But I would venture to say that nobody here would decide to disband the veterans' drug program where we negotiate drug prices in favor of moving that to a Medicare-type D system. I don't think anyone is going to put a bill up like that because I think we all know that our veterans get much better pricing than people under Medicare Part D because we negotiate for prices. And that is the ultimate answer to this, and I yield back.

Mr. Peters. Thank you.

Mr. Burgess. Will the gentleman yield?

Mr. Peters. Sure. Give me a little time at the end there, Doctor.

Mr. Burgess. I just, since the gentleman from New Mexico brought up about former FBI director Louis Freeh, Mr. Chairman, I wanted to ask unanimous consent to insert for the record the full copy of the Report on the Potential Impact of Drug Importation --

The Chairman. Without objection.

Mr. Burgess. -- Proposals on U.S. Law Enforcement.

The Chairman. Without objection.

[The information follows:]

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

Mr. Burgess. And I yield back to the gentleman from California.

Mr. Peters. Thank you very much. I just want to say a lot of people on this committee have been here for a long time, I have not. And a lot of people have had the benefits of hearings on these issues, I have not. I complained about lack of hearings when we had another last big markup and I feel that it is unfortunate the way that this has come to us.

I would say thank you to Mr. Welch for his vigorous advocacy on this issue. I also particularly paid attention to Mr. Lujan and his excellent questions about this. And I don't think this, one of the results of this is that this issue is going away today. I just think this is an unfortunate way for this first to come to the newbies on this committee. And with that Mr. Chairman, I will yield back.

The Chairman. Are there other members seeking recognition? The chair recognizes the gentleman from Ohio, Mr. Latta, for 5 minutes.

Mr. Latta. Well, thank you, Mr. Chairman. And if I could follow up on the gentleman's comments from New Mexico, I was the author of the track and trace legislation and before I got it, it was going on for quite a few years in this committee and it was very, very difficult to get a piece of legislation put together. We got it put together, but again as we discussed a little bit earlier, you know, what we are looking at here is to

make sure we don't have counterfeit, adulterated type drugs being transmitted through the system.

And when we were working on the legislation, again it took a lot of work because we started with the manufacturer and working it all the way down to the corner drugstore that we had to make sure that everything in between from the wholesaler, and we had the transportation in there, everyone had to be involved in this because we were looking at going from right now from a lot to a unit so you know exactly where every one of those pills is going to have been.

So it is one of those things that we want to make sure that in our supply chain we know exactly where it is, because again that took a lot of work from a lot of people and it was a bipartisan effort in this committee. We had Republicans and Democrats put a lot of hours in this, and again it is to make sure that the American people know that when they are getting something that they know exactly where it has been, because as again as I said that you don't want anything that has been adulterated and you don't want anything that is counterfeit.

So that is one of the concerns is that if you bring something in from another country is how does it come into the same system that we have already put in, and it is pretty stringent, to make sure we get there. And I know that again my friends on both sides of the aisle worked on this to make sure we came up with a very good piece of legislation. So I think it is really important that

we remember that, that that track and trace legislation that we did was to protect the American consumer to make sure that they had a drug that they knew was not adulterated and that it was not counterfeit when they receive it.

And Mr. Chairman, I yield back. I yield to the gentleman from Georgia.

Mr. Carter. Mr. Chairman, I get the sense here that escalating drug prices are becoming a partisan issue. And I want to make sure, I want to make sure that we all recognize that that is not the case. This is a bipartisan issue. I can assure you that members on this side of the dais are just as concerned as members on the other side of the dais. This is something that we have got to address.

I think this is the third time I have mentioned we have a commitment from the chairman, from Chairman Walden as well as Chairman Burgess that we are going to address this issue. This underlying legislation here helps us. It helps with more competition. It helps to lower costs. There is more to be done, there is no question about that.

I especially want to thank Representative Lujan for mentioning the middle man, the PBMs. The most effective and the quickest way that we can address escalating prescription prices is to address the middle men that are involved and we are going to be doing that. The PBMs, the ones that bring no value whatsoever to the system but instead are causing prices to

increase. But this will be done, it is just this is not the time to do it right now. And I thank you, Mr. Chairman, and I yield back.

Mr. Welch. Will the gentleman yield?

Mr. Latta. I yield to the gentlelady.

The Chairman. Who did you want to yield to, Mr. Latta? Mr. Latta controls the time, so.

Mr. Latta. To Anna.

Ms. Eshoo. Thank you very much, Mr. Latta. We had some time ago this year testimony at the Health Subcommittee. I don't remember the name of the gentleman, but we can get that. The point that I want to make is that I think that we need to have some hearings on this to really develop a full sense of everything that is related to this issue. It is not a simple, clear-cut, black and white issue. It just isn't, I wish it were. It would be easier to go after.

Now this gentleman testified that 11 percent of drugs account for 63 percent of the spending, so do we upend the entire system in our country? We are trying to get the names of these drugs now from the gentleman that gave this testimony. So I have a deep appreciation for what Peter is doing and he is very committed to the issue of reimportation.

I think that there -- and I have shared this with him, I think that there are some very serious issues that are attached to that but I think that the committee would benefit enormously from

knowing what do the PBMs do? I mean are they additive or are they essentially throwing sand in the gears that end up having people pay more? There is a whole series of issues that are attached to this.

I mean if the Congress for instance -- I would just throw this out. What if the Congress sat down with the pharmaceutical industry and said we are willing to extend the life of your patent not from when it is approved but from when you first enter the door of the FDA, and in return for that we want negotiated drug prices? We do it with the VA, why can't we do it across, you know.

I mean it is just an idea, but I think that we need to really do a deeper dive and examine all of these things and not be afraid of who comes forward and what they say. Put all the issues out on the table so that we have all of these things that are part of the record because it is an issue in our country. It is an issue for all of us, for all of our constituents. Now I really think that is the most prudent way to go forward. So I appreciate Mr. Latta yielding time to me.

The Chairman. The gentleman's time has expired.

Ms. Eshoo. Thank you. Yes, I know that. Thank you.

The Chairman. The gentleman from Maryland is recognized for 5 minutes.

Mr. Sarbanes. Thank you, Mr. Chairman. I expect to support the amendment. I am doing it really as a kind of primal scream against the practices of the pharmaceutical industry and on behalf

of many Americans that Peter has already described and other members who feel just like every day they are getting rolled over by those industries.

I don't think the underlying amendment -- I don't think the amendment is perfect. In fact, I think that there are legitimate concerns that have been expressed by Representative Lujan and some other members from the Republican side of the aisle, concerns about safety, how you can really track and trace these drugs, whether once you authorize a program like this it opens the opportunity for really unscrupulous actors to get into the mix in a way that could potentially harm people.

And I hope that ultimately if we are able to put a program like this together that we will put the resources behind the FDA and whatever other resources are needed to make sure that the safety concerns can be addressed. But in some way my vote today in support of this is almost disconnected from the substance of the amendment itself. It is really about as Congressman Doyle said, sending a message, a wake-up call to the pharmaceutical industry, and I expect that there is probably a few representatives of that industry in the audience today. That people have just gotten to the end of their tether on this and they are tired of price fixing, they are tired of price gouging, they are tired of price holding. These practices have got to end.

And on this day, this bill is our opportunity to send that message. That is what it is. It is an opportunity to send a

message to the industry that business as usual has got to change. And I agree with every single person who said that it is a responsibility, it is an obligation of this committee. This is the jurisdiction that we have to hold meaningful hearings and to try to get to the bottom of this. There is too many people out there that are hurting and are depending on us to get to the bottom of it.

So I will return to what I said at the outset. This vote is a primal scream on my part and on behalf of many out there who just want these practices of exploiting innocent Americans who are sick and need these medications to say to the industry enough is enough, we need to do something about it. And I will yield time to Mr. Welch.

Mr. Welch. And thank you very much, Mr. Sarbanes. I want to say a couple of things. Number one, this is definitely a bipartisan issue. Every single one of our constituents is affected by it. Number two, I really do believe in competition, so let's just say for a moment that this importation would be safe, and I understand that is a very fair question and you can't compromise. But if it is safe, then why not give the option to a consumer to get the better value in Canada versus the higher price in the U.S.? That is the way competition works.

You know, when I met with President Trump, an analogy came up about if you are a purchaser by definition you try to get the best price you can. If you are seller you try to get the best

price you can. In the case of these prescription drugs, the U.S. is a big purchaser in our VA where we do negotiate and our Medicare where we don't. And it is a fair competitive situation where the bulk buyer says I want to get a better per unit price. So it would be like the President in one of his buildings buying a thousand mirrors and paying the same per unit price as if he were buying ten.

So, you know, I think, Mr. Shimkus, competition really is important and if we have it, it is going to work, but my view is we don't have it. And we don't have it in the exclusivity period because we made a public policy that the necessity of that is to get the benefit of those pharmaceuticals, but beyond that there is all kinds of gaming going on.

And if we can deal with safety, and I think I have in this legislation but I understand that you are going to have to make your own judgment on that, then why not give the purchaser the option to get the better price? I yield back, but I thank the -- by the way, one last question.

Mr. Chairman, this is bipartisan, but I think on our side two things are really compelling, this price negotiation issue and my request, and I bet a lot of us would agree with this. Could we have a hearing on price negotiation? This issue of drug importation has been around a really long time. Legitimate debate issues, can we have a hearing on importation?

The Chairman. So the gentleman's time has expired. Let me

suggest that there is work underway already in the investigative subcommittee on some of the pricing issues. As you know, this committee has a long and proud tradition of doing work on different issues. I was here when we did investigation on importation issues and had a hearing. I was on the Oversight and Investigations Subcommittee.

You will find in the Freeh report that was just issued, there is some shocking problems as I think members on both sides of the aisle are aware of we share the notion that price matters. We also know we want safety, and I have heard it from other members, both sides of the aisle.

But it is not just drugs. What we have to look at is from one end of the healthcare system to the other what is driving up the cost of healthcare and where is the squeeze? Whether it is in the hospitals or the pharmacies or the doctors or the PBMs or the you name every piece of it, my commitment is we are going to look at every piece of this and try to get to the answer regardless of who is involved.

I would suggest that given the time we have in the committee we have some of this work to do that takes precedence, reauthorizing FDA as we have heard we are trying to make bipartisan. Clearly your amendment doesn't achieve that goal, but I understand your desire and your passion and your commitment to raising this issue.

The second piece is that while we are looking at these issues

we also have to reauthorize SCHIP and community health centers this year. Those we have to do based on the calendar, but our subcommittees can be doing other work especially in O&I on some of these other issues. And as Mr. Carter and I have talked, he has very passionate concerns about a part of this chain. You have passionate concerns about other parts. Whoever I am not with tells me about all the problems in the other parts of the chain, and so fundamentally we as a Congress need to look at the whole thing.

So I am not going to commit today to a specific hearing on a specific piece of this, but suffice it to say for the American people, for all of us, we have got to figure out why is the whole thing costing as much as it is and is there a way to get the squeeze out of it. And so that is my commitment to you.

Just for the record, we are going to have votes on the floor. I know that we have a couple of other perhaps amendments and may be more dependent about what happens with this amendment and we will probably have to come back after votes unless we are able to resolve these now. I don't know if you plan to ask for a recorded vote or withdraw or what, but just for purposes -- as you know I am willing to stay here for, I can order breakfast if you want. But I don't think anybody wants a new T-shirt, so hey, it is up to you. I am here to be the gentle chairman.

So are there other members seeking recognition? I think we are back to this side of the aisle, or would we like to call the

question? Does the gentleman want to -- wants the question. Those in favor will vote aye. Those opposed, no.

Those in favor will vote aye.

Those opposed, no.

The noes appear to have it. The noes have it and the amendment is not agreed to.

Are there further amendments to be considered?

Mr. Guthrie. Mr. Chairman, I have an amendment at the desk.

The Chairman. For what purpose -- the clerk will report the amendment.

The Clerk. Amendment to Committee Print of H.R. 2430 offered by Mr. Guthrie of Kentucky.

[The Amendment offered by Mr. Guthrie follows:]

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

Mr. Guthrie. Thank you, Mr. Chairman. The need to ensure timely and robust communications between medical product developers, payers, and other population health decision makers is more important now than ever, particularly if we are going to shift towards a value-based payment system in this country.

In 21st Century Cures we updated Section 502(a)(1) of the Food, Drug, and Cosmetic Act to clarify how pharmaceutical manufacturers could discuss healthcare economic information with payers after their products are approved by FDA without being considered false or misleading under the act. This amendment would build on our efforts in 21st Century Cures by providing a statutory safe harbor for medical product manufacturers to communicate with payers and similar entities about clinical and economic information relating to investigational products and new uses prior to FDA approval.

Payers, benefit managers, and integrated delivery systems have stated that they need this information at least 12 to 18 months prior to FDA approval in order to plan, budget, and forecast accordingly. This amendment would allow for necessary information exchange in a responsible, confined manner to encourage better decision making on the part of payers and other population health decision makers.

These are sophisticated, skeptical audiences that are rightfully asking for more data early in the process. I urge my colleagues to support this amendment.

The Chairman. And yield back?

Mr. Guthrie. I yield back.

The Chairman. The gentleman yields back the balance of his time. The chair recognizes the gentleman from New Jersey for 5 minutes.

Mr. Pallone. Mr. Chairman, I move to strike the last word and speak in opposition to the amendment offered by Mr. Guthrie. The amendment would allow for communication of healthcare economic information and scientific information about an unapproved drug or device or an unapproved use of a drug or device as long as the manufacturer intends to submit an application.

This approach is dramatically broader than that contemplated by FDA in the agency's recent January 2017 guidance. That guidance would have permitted for the communication of truthful, accurate, and non-misleading information that could include the anticipated timeline for FDA approval or clearance, product information and pricing, marketing strategies, factual information from clinical or preclinical studies, as well as information about the indications sought in the population being studied.

However, this guidance also included important safeguards by requiring manufacturers to also make clear that the product is still under investigation and that the product has not been found to be safe or effective. The manufacturer would also have to provide information regarding the stage of development of the

product and any changes in information related to review status or progress or failures in the clinical study.

This legislation would blow a hole in the current approval process by allowing the communication of any scientific evidence or healthcare economic information to payers or formularies without any recourse for the FDA to prevent bad actors from communicating false or misleading information. It would also hamstring FDA from considering the product to be misbranded.

Broadening communication in this way would undermine FDA's regulatory review process as well as the safety and effectiveness approval standard which is the gold standard across the globe. Erosion of this gold standard only damages consumer and healthcare professional trust and confidence in FDA's approval process. Allowing manufacturers to communicate about unapproved products and unapproved uses of their products reduces the incentive to go through FDA's approval process and thereby reduces the incentive to conduct large, well-controlled, randomized clinical trials that would prove a product is both safe and effective.

Again, if my colleagues are sincere about ensuring the communications of accurate, truthful, and non-misleading scientific and healthcare economic information about unapproved products prior to approval, then this committee should undertake a thorough examination of this issue that fully contemplates both the risks and the benefits of expanding these types of communications and have a robust dialogue with a wide range of

stakeholders, manufacturers, payers, patients, and healthcare professionals. We should not be trying to rush a proposal through in the dark of night without careful consideration and conversation.

So Mr. Chairman, I want to make it quite clear that I have always said that the most important thing that we do when we are talking about drug approvals is to make sure the drugs are safe. And when I talk about the gold standard, you know, we went on a trip that Fred Upton sponsored 2 years ago where we were with, we were at the European Union and we talked about drug approvals. The one thing that has always characterized the American approvals process is the guarantee of safety or at least the guarantee as much as possible of safety.

And my real concern is today that this amendment, and I know if the Griffin amendment is proposed as well, compromises or has the potential -- I know that is not the intent obviously of the authors, but has the potential to compromise safety and I think it is a mistake to have these amendments included in a bipartisan bill. We have worked this bill out. We have worked with industry. We have worked with administration. And we have a bipartisan bill that I was prepared to support obviously as one of the sponsors.

But I cannot support the underlying bill if this, or I should say the bill if this amendment or the Griffin amendment are added to it because I have always said that I will never do anything

as a member of this committee or as the ranking member that would compromise safety, and I seriously worry that the potential exists if this or the Griffin amendment would pass.

So I would urge my colleagues to oppose this amendment, and if it does pass I would urge my colleagues to oppose the bill. I yield back.

The Chairman. The gentleman yields back. Are there other members seeking recognition on this issue? On the Republican side? If not, we will recognize the gentleman from Texas, Mr. Green, for 5 minutes.

Mr. Green. Thank you, Mr. Chairman. In my opening statement I talked about adding amendments that would hurt the basis of the bill. Our consensus on the legislation in this area is difficult to achieve, certainly not in the time we have. The bill we are looking at was basically a reauthorization that has been done for 2 decades, and we had legislative hearings, this issue was not brought up.

Off-label communication is highly controversial. It has allowed for users of drug products that have not been proven to be safe or effective exposing patients to potential harms. Legislation in this area could have unintended consequences, potentially undermining FDA's approval standard and exposing patients to unnecessary risk. We need to ensure that we better understand the implications.

That is why I think we ought to have a separate healthcare

subcommittee on this issue. Legislation is premature. The FDA has ongoing rulemaking in this area and has recently extended the comment period to July the 9th, allowing stakeholders including the pharmaceutical industry the opportunity to work with FDA to address the appropriate scope of intended use. Off-label communications were not the subject of any of hearings and as I said was not debated over the course of the last months where we have been working collaborative on this user fee agreement reauthorization. We have not had a responsible amount of time to consider the implications of this policy.

I would be open if my chair of the subcommittee and chair of the full committee would have a hearing on it in our subcommittee. And like my ranking member, I intend to vote no against this amendment and it would actually make me have to vote no on the full package if this amendment passes. And I would be glad to yield to someone who wants some time. I yield back.

The Chairman. The gentleman yields back. At this point we do have votes on, on the floor, so I am going to recess the committee and let's return immediately after votes to continue on. The committee stands in recess.

[Whereupon, at 1:59 p.m., the committee recessed, to reconvene at 3:03 p.m., the same day.]

The Chairman. I call the full committee, the Energy Committee, the Energy and Commerce Committee to order, and I want to welcome everybody back. I will give you time to get into your

seats as we begin to proceed here. When we took a break for votes we were on the Guthrie amendment and Mr. Guthrie had offered and spoken on that amendment. I would be inclined now to recognize the gentleman from Virginia, Mr. Griffith, for 5 minutes.

Mr. Griffith. Thank you, Mr. Chairman. I appreciate it very much. I had an amendment at the desk that somewhat resembled my House Resolution 1703. And as I previously discussed at subcommittee, there is a long overdue need for Congress to clarify how medical product manufacturers can responsibly engage in a meaningful dialogue communication about data and information that is not included in their product labeling. The amendment or the bill responsibly clarifies some key terms and concepts in the statute interpretations and applications which have stifled constitutionally protected and medically valuable information from being shared.

Now I believe that the FDA's current policy impedes constitutionally protected commercial free speech and I believe it is time for us to act and responsibly set up clear rules of the road before the courts become the de facto decision maker on this issue. I think a greater threat to safety is a failure to act on this and have a court strike down the FDA's policies as being a violation of the constitutionally protected commercial free speech.

We saw this once before related to compounding drugs, and we found that two circuits knocked it down. The FDA didn't seem

to understand commercial free speech, they then failed to act and we ended up with the NECC as an indirect result of that, the NECC problem in which many people died or were severely injured. So this is not something that I take lightly.

That being said and understanding their concerns, since I first introduced the bill and then we talked about it in the subcommittee I have a made a number of changes to the bill. Now it is important to remember that the original bill as introduced was already significantly narrower than previous legislative language that was subject to deliberations in the past Congress.

So what we did was first I heard that the bill would reduce standards under which drugs can be advertised. This is not accurate, but to be cautious the revised language in the amendment that we would have offered, which I am happy to share with the other side at any time, makes it abundantly clear that in order for a communication to be covered by the scientific exchange safe harbor in the bill it may not be advertising or otherwise promotional in nature.

Second, I heard that the evidentiary standard used in the bill as introduced is too vague and unenforceable. The updated language makes it clear that any such communication must be supported by competent and reliable scientific evidence, a standard that is well understood by the FDA and would limit the type of information privy to this safe harbor. Further, the courts have been consistent in explaining FDA's extremely limited

ability to restrict truthful and non-misleading off-label communication. Therefore any further narrowing of the standard applied would be constitutionally suspect.

Third, I have heard that companies could cherry pick data and present this information out of context and in its best light. This is a legitimate concern, and the updated language makes it clear that in order to fall under this safe harbor the communication must clearly disclose limitations of the data and any contradictory information known to the manufacturer.

Last, I heard concerns about various activities included in the informative list of communications that would qualify for this scientific exchange safe harbor, so I removed the list so we don't have that issue.

Now Mr. Chairman, I am more than willing to continue to work on this since it is my understanding that we have gotten some assurances that we can work on this. But I do think it is important recognizing that this committee should be setting this path and not be relying on our courts to come in and just strike down what the FDA has and then create a system where there are no rules and in which communication and all the fears that members have raised would in fact would become reality until we then were able to take action later. I would rather act in advance than to wait until we have a problem.

And so Mr. Chairman, I hope that we can resolve this matter. It is obvious that companies are hesitant to share information

and at some point they are going to feel they have no choice but to go to the courts. And so I want to preempt that by coming out with constitutionally sound, reasonable rules of the road for us to move forward. And with that I can yield back or I can yield to Mr. Guthrie, whichever you prefer, Mr. Chairman.

The Chairman. Why don't you yield to Mr. Guthrie?

Mr. Griffith. I will do that. I yield to Mr. Guthrie.

Mr. Guthrie. Thank you, Mr. Chairman. And I appreciate the concerns of the ranking member brought forth on safety, and I also appreciate that he said he is sure it wasn't the intent of either the sponsors of these amendments and certainly not -- our object is to try to move towards a more value-based payment system.

We talked about drug prices earlier. That is what our intent is with this. And for instance, we had the hepatitis C drug that came out that was expensive and the plans hadn't prepared for it, hadn't prepared for it. And I in no way want an unapproved drug to be promoted and advertised, but I do think it is appropriate when it is moving down the pathway towards being approved that sophisticated players in the system, that the payers, the PBMs, the payers, the health plans can sit down with the drug companies and get the information so they can plan.

They say they need this information 12 to 18 months ahead of time. I think that you are talking about sophisticated negotiators not trying to advertise publicly to the public and it allows health plans to start pricing, you know, some people

say, well, if you have a hepatitis C drug it is expensive but you are not going to have liver failure, which is more expensive. And so it allows that value-based to go forward. I think it is an important group moving forward.

I know I am over my time, but with reassurance of all parties that we can work on this and make sure we do cover, because I don't want to have any exposure to safety, but we do make sure those concerns are covered but allow plans and pharmaceutical companies to come together preapproval, so when the product is approved and is on the marketplace and it is effective then people can have that service instead of waiting through another round, so the insurance companies and the PBMs can price it actuarially and put it into their budgets.

So I think this actually brings the product not to the marketplace faster because FDA decides that, but it puts in the hands of the consumer faster because their payers, their insurance companies decide in a lot of ways what they were willing to pay for which gives people access to these important drugs. And that is what we are trying to do here, so if there is some reassurance I will withdraw my amendment with no objection.

The Chairman. At this time, before you withdraw, I would yield to my friend from New Jersey maybe for purposes of a colloquy. I know you --

Mr. Pallone. Sure.

The Chairman. He and I have had a discussion about this and

I will yield to him first and then we can proceed.

Mr. Pallone. Thank you, Mr. Chairman. I just want to, I recognize that members care about the off labeling or off-label communications issue, which I think is the subject of both the Guthrie and the Griffith amendment, but I just as I said before, I don't think it makes sense to deal with this or rush it through and attach it to the FDA user fee authorization because this is a must-pass bill.

We have worked on it. We have always done it on a bipartisan basis. And I would hate to see it, the off-label communication issue, you know, derail it or slow it down because I do believe we need to get this bill passed, get it to the Senate, get the President to sign it so we avoid layoffs and other problems at the FDA.

But I will certainly agree to work with the majority to address the off-label communication issue through regular order, again outside of the user fee issue because I do think it is something we need to address, Mr. Chairman.

The Chairman. If the gentleman would yield, I appreciate the gentleman's comments and concerns. I want to commend Mr. Griffith and Mr. Guthrie for their diligence, diligence and hard work on these two really important issues. It was my hope that we would be able to include them on this in a bipartisan way. Clearly that was not going to occur today, so I appreciate your indulgence on it.

And I appreciate your commitment to work with us in the near term in regular order to resolve the differences that are there, because I think this is clearly a place where the Congress should insert itself and not leave this to ad hoc decisions in the courts and that we could achieve better pricing policies if we had better communication.

So I appreciate my colleagues on the Republican side willingness to bear with us to make sure that the user fee agreement bill can move forward on I believe it will be unanimous basis or certainly bipartisan, because this is critical to move forward. You have my commitment that we will step up the pace on these two issues as we work up other bills and get after this as well, because I think it is overdue. I think it is something the committee should address.

And Mr. Pallone, I appreciate your willingness to work with us on these matters, and with that I would recognize the gentleman from Kentucky.

Mr. Guthrie. Thank you. I certainly understand we have got to move the user fee forward and in a bipartisan basis. I hope in the future working together we can do the off-label communication in a bipartisan way, and so with that I withdraw my amendment.

The Chairman. The gentleman withdraws his amendments. Are they are any other amendments to come before the committee? If not, the question now arises on favorably reporting H.R. 2430,

as amended, to the House.

All those in favor will say aye.

Opposed, nay.

The clerk will call the roll.

The Clerk. Mr. Barton?

Mr. Upton?

Mr. Upton. Votes aye.

The Clerk. Mr. Upton votes aye.

Mr. Shimkus?

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Murphy?

Mr. Murphy. Aye.

The Clerk. Mr. Murphy votes aye.

Mr. Burgess?

Mr. Burgess. Aye.

The Clerk. Mr. Burgess votes aye.

Mrs. Blackburn?

Mrs. Blackburn. Aye.

The Clerk. Mrs. Blackburn votes aye.

Mr. Scalise?

Mr. Latta?

Mr. Latta. Aye.

The Clerk. Mr. Latta votes aye.

Mrs. McMorris Rodgers?

Mrs. McMorris Rodgers. Aye.

The Clerk. Mrs. McMorris Rodgers votes aye.

Mr. Harper?

Mr. Harper. Aye.

The Clerk. Mr. Harper votes aye.

Mr. Lance?

Mr. Lance. Aye.

The Clerk. Mr. Lance votes aye.

Mr. Guthrie?

Mr. Guthrie. Aye.

The Clerk. Mr. Guthrie votes aye.

Mr. Olson?

Mr. Olson. Aye.

The Clerk. Mr. Olson votes aye.

Mr. McKinley?

Mr. McKinley. Aye.

The Clerk. Mr. McKinley votes aye.

Mr. Kinzinger?

Mr. Kinzinger. Aye.

The Clerk. Mr. Kinzinger votes aye.

Mr. Griffith?

Mr. Griffith. Aye.

The Clerk. Mr. Griffith votes aye.

Mr. Bilirakis?

Mr. Bilirakis. Aye.

The Clerk. Mr. Bilirakis votes aye.

Mr. Johnson?

Mr. Johnson. Aye.

The Clerk. Mr. Johnson votes aye.

Mr. Long?

Mr. Long. Aye.

The Clerk. Mr. Long votes aye.

Mr. Bucshon?

Mr. Bucshon. Aye.

The Clerk. Mr. Bucshon votes aye.

Mr. Flores?

Mr. Flores. Aye.

The Clerk. Mr. Flores votes aye.

Mrs. Brooks?

Mrs. Brooks. Aye.

The Clerk. Mrs. Brooks votes aye.

Mr. Mullin?

Mr. Mullin. Aye.

The Clerk. Mr. Mullin votes aye.

Mr. Hudson?

Mr. Hudson. Aye.

The Clerk. Mr. Hudson votes aye.

Mr. Collins?

Mr. Collins. Aye.

The Clerk. Mr. Collins votes aye.

Mr. Cramer?

Mr. Walberg?

Mr. Walberg. Aye.

The Clerk. Mr. Walberg votes aye.

Mrs. Walters?

Mrs. Walters. Aye.

The Clerk. Mrs. Walters votes aye.

Mr. Costello?

Mr. Costello. Aye.

The Clerk. Mr. Costello votes aye.

Mr. Carter?

Mr. Carter. Aye.

The Clerk. Mr. Carter votes aye.

Mr. Pallone?

Mr. Pallone. Aye.

The Clerk. Mr. Pallone votes aye.

Mr. Rush?

Mr. Rush. Aye.

The Clerk. Mr. Rush votes aye.

Ms. Eshoo?

Mr. Engel?

Mr. Green?

Ms. DeGette?

Ms. DeGette. Aye.

The Clerk. Ms. DeGette votes aye.

Mr. Doyle?

Mr. Doyle. Yes.

The Clerk. Mr. Doyle votes aye.

Ms. Schakowsky?

Mr. Butterfield?

Mr. Butterfield. Aye.

The Clerk. Mr. Butterfield votes aye.

Ms. Matsui?

Ms. Matsui. Aye.

The Clerk. Ms. Matsui votes aye.

Ms. Castor?

Ms. Castor. Aye.

The Clerk. Ms. Castor votes aye.

Mr. Sarbanes?

Mr. McNerney?

Mr. McNerney. Aye.

The Clerk. Mr. McNerney votes aye.

Mr. Welch?

Mr. Welch. Aye.

The Clerk. Mr. Welch votes aye.

Mr. Lujan?

Mr. Lujan. Aye.

The Clerk. Mr. Lujan votes aye.

Mr. Tonko?

Mr. Tonko. Aye.

The Clerk. Mr. Tonko votes aye.

Ms. Clarke?

Ms. Clarke. Aye.

The Clerk. Ms. Clarke votes aye.

Mr. Loebsack?

Mr. Loebsack. Aye.

The Clerk. Mr. Loebsack votes aye.

Mr. Schrader?

Mr. Schrader. Aye.

The Clerk. Mr. Schrader votes aye.

Mr. Kennedy?

Mr. Kennedy. Aye.

The Clerk. Mr. Kennedy votes aye.

Mr. Cardenas?

Mr. Cardenas. Aye.

The Clerk. Mr. Cardenas votes aye.

Mr. Ruiz?

Mr. Ruiz. Aye.

The Clerk. Mr. Ruiz votes aye.

Mr. Peters?

Mr. Peters. Aye.

The Clerk. Mr. Peters votes aye.

Mrs. Dingell?

Mrs. Dingell. Aye.

The Clerk. Mrs. Dingell votes aye.

Chairman Walden?

The Chairman. Walden votes aye. Are there other members not recorded? Mr. Barton?

Mr. Barton. Votes aye.

The Clerk. Mr. Barton votes aye.

The Chairman. Mr. Scalise?

Mr. Scalise. Aye.

The Clerk. Mr. Scalise votes aye.

The Chairman. Mr. Cramer?

Mr. Cramer. Aye.

The Clerk. Mr. Cramer votes aye.

The Chairman. Ms. Eshoo?

Ms. Eshoo. Aye.

The Clerk. Ms. Eshoo votes aye.

The Chairman. Mr. Green?

Mr. Green. Aye.

The Clerk. Mr. Green votes aye.

The Chairman. Mr. Sarbanes?

Mr. Sarbanes. Aye.

The Clerk. Mr. Sarbanes votes aye.

The Chairman. Are there other members who are not recorded? Mr. Engel? Okay, we will wait. That is fine, yeah.

Is the gentlelady recorded?

The Clerk. Ms. Schakowsky is not recorded.

The Chairman. How would you like to vote Ms. Schakowsky?

Ms. Schakowsky. Aye.

The Chairman. Ms. Schakowsky votes aye.

The Clerk. Ms. Schakowsky votes aye.

The Chairman. Any other members not recorded who are here? I think everybody is recorded now. The clerk will report the tally.

The Clerk. Mr. Chairman, on that vote there were 54 ayes and zero noes.

[Applause.]

The Chairman. Therefore, the ayes have it and the legislation, as amended, is adopted. A couple of housekeeping notes, we have a letter from the National Electrical Contractors Association in support of the Energy Infrastructure and Efficiency legislation that I would like to enter into the record. Without objection, so ordered.

[The information follows:]

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

The Chairman. I recognize the gentleman from New Jersey.

Mr. Pallone. Thank you, Mr. Chairman. Pursuant to House Rule 11 Clause 2(l), I am giving notice of our intention to file minority views for inclusion in any legislative reports that this committee forwards to the House on those measures we have considered. Under that rule, the minority is accorded up to 2 additional calendar days to file its views with the committee clerk. And thank you again, I would yield back.

The Chairman. The gentleman yields back. The chair recognizes the gentleman from Texas, Dr. Burgess.

Mr. Burgess. Thank you, Mr. Chairman. I just wanted to for a moment recognize the fact that this is something that happens every 5 years, so it is not a frequent occurrence. I think today's markup was important on the FDA user fee agreements.

And, Mr. Chairman, I want to join you I am sure, in thanking our staff and all of the members of the committee on both sides of the dais, staff on both sides who have worked so hard to bring this thing across the finish line. It was critical that we get this done. Sometimes the country doesn't think we can work together. Today we have proved that we can and I am grateful for your leadership on this, Mr. Chairman.

The Chairman. Thank you.

Mr. Burgess. I yield back.

The Chairman. And you for yours and your ranking member as well. And to all our staff and all our members, good work today.

We are proving once again the Energy and Commerce Committee can deliver. Without objection, staff is authorized to make technical and conforming changes to the legislation considered by the committee today, so ordered. Without objection, the committee stands adjourned.

[Whereupon, at 3:22 p.m., the committee was adjourned.]