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SUBCOMMITTEE VOTE ON H.R. 1222, H.R. 2410,

AND H.R. 2430, FDA REAUTHORIZATION ACT OF 2017

THURSDAY, MAY 18, 2017

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

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

Members present: Representatives Burgess, Guthrie, Barton, Upton, Shimkus, Murphy, Blackburn, McMorris Rodgers, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden(ex officio), Green, Schakowsky, Butterfield, Matsui, Castor, Sarbanes, Schrader, Kennedy, Cardenas, Eshoo, DeGette, and Pallone (ex officio).

Staff present: Grace Appelbe, Legislative Clerk, Energy/Environment; Mike Bloomquist, Deputy Staff Director; Elena Brennan, Legislative Clerk, Oversight and Investigations; Adam Buckalew, Professional Staff Member, Health; Karen Christian, General Counsel; Jordan Davis, Director of Policy and External Affairs; Paul Edattel, Chief Counsel, Health; Blair Ellis, Digital Coordinator/Press Secretary; Adam Fromm, Director of Outreach and Coalitions; Giulia Giannangeli, Legislative Clerk, Digital Commerce and Consumer Protection/Communications and Technology; Jay Gulshen, Legislative Clerk, Health; Peter Kielty, Deputy General Counsel; Katie McKeough, Press Assistant; Alex Miller, Video Production Aide and Press Assistant; Mark Ratner, Policy Coordinator; Kristen Shatynski, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; Danielle Steele, Policy Coordinator, Health; John Stone, Senior Counsel, Health; Evan Viau, Staff Assistant; Hamlin Wade, Special Advisor, External Affairs; Everett Winnick, Director of Information Technology; 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; Dan Miller, Minority Policy Assistant; Olivia Pham, Minority Health Fellow; Tim Robinson, Minority Chief Counsel; Samantha

Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Senior Health Policy Advisor; and C.J. Young, Minority Press Secretary.

Chairman Burgess. I will call the subcommittee to order. I recognize myself for 3 minutes for an opening statement. Today, we will mark up the Food and Drug Administration Reauthorization Act of 2017. This is an important milestone in the work to reauthorize the Food and Drug Administration user fee programs. The Food and Drug Administration began holding public meetings on these agreements in 2015 and Congress received the Food and Drug Administration and industry's proposed commitment letters in January of this year. This subcommittee has held four legislative hearings on the substance of this bill, as well as several of the amendments that we will consider today.

Today's markup is just the latest step in nearly2years by the biopharmaceutical and medical device industry, the Food and Drug Administration, and Congress. This bill is bipartisan. This bill is bicameral. It is a priority to complete this work and reauthorize the user fee programs in a timely manner.

In each of our hearings, we have heard about the tremendous success of the user fee programs in expanding access to affordable medications, supporting biomedical innovation, and maintaining high standards of the Food and Drug Administration for safety, efficacy, and quality. The Food and Drug Administration Reauthorization Act will build

on these successes, as well as the achievements in the 21st Century Cures bill and ensure that the FDA has the resources necessary to get medical treatments and cures to patients and healthcare providers as quickly as possible.

I certainly want to thank Chairman Walden and Ranking Member Green, Ranking Member Pallone, and all of the members of this subcommittee for working in concert to improve the substance of this bill and certainly we all look forward to sending it for presidential signature in short order.

In addition to the Food and Drug Administration Reauthorization Act, we will also be considering two important public health bills. Representative Bilirakis has an amendment in the nature of a substitute to H.R. 1222. This bill will take several important steps to save and improve the lives of infants and adults affected by congenital heart disease.

And finally, I would like to speak in support of H.R. 2410, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017. This bill was introduced by Representative Davis and myself would further our commitment to helping those with sickle cell disease by increasing our commitment through research, surveillance, prevention, and treatment through federal collaboration with local and community-based entities. Having cared for

patients with sickle cell disease as a physician at Parkland Hospital, I have seen first hand the devastating effects that this can have on people, patients, and their families. This bill provides an important step forward in ensuring that we have the resources to better understand this disease and to maintain access to the services for those affected by sickle cell disease.

I would like to thank again all of the members of the subcommittee. I know we have all put in a tremendous amount of work on this product. I look forward to advancing it to the full committee. I yield back my time and recognize the ranking member of the subcommittee, Mr. Green of Texas, 3 minutes for an opening statement, please.

Mr. Green. Thank you, Mr. Chairman. This is the kind of markup we like. All three of our bills, of course, we have worked on FDA reauthorization much more. We had a number of hearings, but let me first talk about H.R. 1222, the Congenital Heart Futures Reauthorization Act. It was introduced by a colleague on our committee, Congressman Bilirakis and Congressman Schiff from California. It is really important for reauthorization and I am glad our subcommittee is doing these reauthorizations to make sure we have everything lined up so we can request funding for the programs through the appropriations process.

Our next bill is 2410, the Sickle Cell Disease Research Surveillance, Prevention, and Treatment Act, both by the chair of our Health Subcommittee, Congressman Burgess and Congressman Davis. Again, this is very important for the research and it authorizes a particular research program so we can get money from the appropriations process.

Now on the FDA reauthorization, we have a package of four user fee agreements that reauthorized key FDA capabilities to review and evaluate medical products on behalf of the American people. It is critical that these programs be reauthorized in a timely manner. Failure to do so will halt clinical trials, grind research to a halt and to put new therapy pipeline in jeopardy.

We have had hearings on the underlying agreement and they have what I would call a lovefest. Much progress has been made since the first user fee agreement was made in 1992. I am pleased that we are advancing these four negotiated products today.

One of the issues, the over-counter monograph reform in establishing a user fee program for OTCs is a critically-important issue and I hope to continue working with my colleagues in our committee to advance these critical issues.

We also are considering several amendments which are bipartisan in nature and will improve our nation's overall

health. I look forward to learning more about these amendments from members today and moving forward. And I will yield back my time, Mr. Chairman.

Chairman Burgess. The chairman yields back. The chair thanks the gentleman. The chair yields to the gentleman from Michigan 2 minutes for an opening statement, please.

Mr. Upton. Thank you, Mr. Chairman. Those who know me know that I have got a long record of supporting innovation when it comes to research and development of new drugs and devices. That is why I was proud to sponsor the 21st Century Cure Act with my colleague, Diana DeGette. This bill broke down the barriers for research and development, putting a greater focus on patient-centered care and gave billions of dollars in resources to the NIH. President Obama signed our bill into law in December last year. It marked a truly great victory for patients and researchers across the country.

Now that it is law, we have got to make sure that the FDA is able to handle new breakthrough treatments in a timely and predictable fashion, all while still maintaining the highest levels of patient safety. That is why these user fee agreements are so important.

My district in Michigan has literally thousands of jobs that are impacted by the legislation, whether it be on the drug side with Pfizer's plant in Portgage, Michigan or the

device side at Stryker's headquarters and manufacturing facilities in Kalamazoo, or the generic side at Perrigo in Allegan. Passing this legislation is vital to these good paying local jobs and prevents the FDA from laying off literally 70 percent of the folks that they have working on approvals. It is important that we do this expeditiously. I yield the balance of my time to Dr. Murphy.

Mr. Murphy. I thank the gentleman from Michigan. I want to comment on -- I know we are going through this and I thank the chairman for moving these bills through committee. On one of them I want to comment. Mr. Costello of Pennsylvania will be offering an amendment when this goes to full committee on some of the issues involving medical devices with regard to third party persons who service them and making sure the FDA is working with them to certify them so that we end up with quality services throughout that and that this is something that we are fully aware of. So I do want members to know that that amendment will be coming forth and it will be a good one for us to review and support at that time. I yield back.

Chairman Burgess. The gentleman yields back his time. The chair now recognizes the ranking member of the full committee, Mr. Pallone of New Jersey, 3 minutes for an opening statement, please.

Mr. Pallone. Thank you, Mr. Chairman. Today, we are considering three bipartisan bills that will reauthorize CDC's congenital heart disease programs, sickle cell disease prevention and treatment demonstration program, and FDA's medical product user fee program.

H.R. 2430, the Food and Drug Administration Reauthorization Act would reauthorize FDA's user fee programs in the areas of prescription and generic drugs, biosimilars, and medical devices. This bill is the product of considerable discussion and negotiation between FDA, industry, and additional stakeholders and also incorporates the bipartisan, bicameral work of this committee and the Senate.

So with passage of the user fee reauthorization package will ensure that FDA layoffs will not occur and that the medical product review process will continue uninterrupted, ensuring patient access to the medical treatments that they need.

I am disappointed that the Trump administration is pushing at the last hour to reopen renegotiations on the user fee reauthorizations in order to withhold Federal Government support for the critical work that is at the heart of FDA's public health mission. The Trump administration should seriously reconsider any reopening of these negotiations.

Instead, we should move forward with this bipartisan bill that will allow the FDA to meet its mission of ensuring the medical products that patients and American families use are safe and effective. And I hope that all of my colleagues will reject this proposal and continue the process to reauthorize the user fee programs as agreed to by the FDA and industry.

Mr. Chairman, I did want to raise, however, the issue of drug pricing in the time that I have left. Prescription drug prices are rising at an alarming rate and the problem is widespread. Annual drug spending in the United States is estimated to reach more than $500 billion by 2018 and in 2014, spending grew by 12 percent, faster than any year since 2002. And this increase is having a real impact on American families with 1 out of 5 Americans, age 19 to 64, unable to afford the cost of their prescriptions.

Throughout the country, and even from our president, there is bipartisan support for action to lower the cost of prescription drugs and make treatments more affordable for patients and their families. Yet, despite this commitment from the president, our committee has yet to take a serious look at what can be done to address the high costs of prescription drugs.

So I want to call on the president and my colleagues on

the committee to work with us to have a serious policy discussion in how we can work together to find policies that will truly help to reduce drug prices. And I think that work should begin immediately. So I urge the chairman to hold a hearing on this issue and to begin a process where we can work together in a bipartisan manner as we are today, to learn more about what can be done to make prescription drugs affordable for patients and their families. I yield back.

Chairman Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from Illinois, Mr. Shimkus, 2 minutes for an opening statement. No.

Does anyone on the majority side seek time for an opening statement? The gentleman from Florida, Mr. Bilirakis, is recognized for 2 minutes for an opening statement.

Mr. Bilirakis. Thank you, Mr. Chairman, I appreciate it. Thank you for holding today's markup so we can take these positive steps forward to help patients. I am very glad that we are considering the Congenital Heart Futures Reauthorization Act, a bill I introduced to improve the lives of the nearly 40,000 babies born each year with congenital heart defects. The bill reauthorizes CDC surveillance program of congenital heart defects and ensures important NIH

research continues.

I am also pleased the committee is moving a bill I co-sponsored, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act. Sickle cell disease is known for its prevalence in the African-American community, but it also impacts the Greek community and other Mediterranean communities.

While it is great news that the committee is moving the FDA user fee bill, this will reauthorize the user fee program and make reforms through the FDA to bring about greater efficiency.

I am also proud that the language I worked on with Representative Schrader to lower drug costs will be part of the reauthorized user fee program and I truly believe this reauthorization will improve the FDA.

However, I want to take a moment to talk about the OPEN Act, a bipartisan bill that I introduced with my colleague G.K. Butterfield. OPEN Act would provide an incentive for companies to get mainstream drugs approved for a rare disease. It has the support of over 150 rare disease groups and passed the House in a bipartisan fashion within the 21st Century Cures Act.

When 95 percent of rare diseases have no FDA approved treatments, we can't sit by and do nothing. I hope that as

we move forward with FDA user fees, we can revisit this important legislation and try to help the 30 million Americans suffering from a rare disease.

I yield back, Mr. Chairman. Thank you.

Chairman Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentlelady from California for 2 minutes for an opening statement.

Ms. Matsui. Thank you, Mr. Chairman. I am pleased that our committee is working together in a bipartisan manner to reauthorize the user fee agreements that help to fund the FDA. The FDA ensures that drugs and devices in the U.S. are safe and effective and we cannot take that important role for granted.

However, I must say that FDA could approve all of the safe and effective treatments in the world, but it wouldn't matter if no one could afford them. If people don't have access to health insurance that covers necessary treatments like prescription drugs, chemotherapy, or pacemakers, then the existence of those treatments doesn't help them.

I am extremely concerned by the bill that passed in the House. Instead of taking coverage and essential health benefits away and charging people with preexisting conditions more, we should build on the work that we did in the ACA to make coverage affordable by examining policies in this

committee that would keep the cost of prescription drugs down. We need to ensure that we are encouraging innovation and development of new drugs and treatments, especially for diseases that we don't know enough about like those of the brain, like Alzheimer's and mental illness. But at the same time we need to ensure that when those drugs and treatments come out the other end, they are not prohibitively expensive. I am discouraged that our committee has yet to have a hearing to discuss this topic in earnest and bring in witnesses to help shed light on the complicated process that results in final drug prices. There are many ideas out there to fix the problems, but there is no single silver bullet. So we really need to dig in and work across the healthcare industry to find solutions so that patients are not stuck with the bill. Thank you and I yield back.

Chairman Burgess. The chair thanks the gentlelady. The gentlelady yields back. The chair recognizes the chairman of the full committee, Mr. Walden, 3 minutes for an opening statement, please.

The Chairman. Good morning, Mr. Chairman, to my colleagues. Today, we mark up three bills. Two are public health bills that received hearings last Congress and garnered strong bipartisan support. The other bill is the Food and Drug Administration Reauthorization Act of 2017

which I introduced earlier this week along with Ranking Member Pallone, Chairman Burgess, and Ranking Member Green. This legislation is really critically important for patients, drug and device manufacturers and the entire healthcare sector.

We have all read about medical innovations that once seemed like wishful thinking coming to fruition now. And at a recent hearing, the FDA told us that more advancements are on the horizon, but not without the legislation we will consider today.

Now that 21st Century Cures has become law, the FDA Reauthorization Act is more important than ever and we must continue to build on these successes and improvements for patients delivering hope for new treatments and cures. The FDA Reauthorization Act 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. These agreements were submitted to Congress in January pursuant to a process laid out in statute and we have been working on a bipartisan, bicameral basis since then to translate these important agreements into legislative language which was first circulated several weeks ago.

Under the leadership of Dr. Burgess, the Health Subcommittee has held multiple hearings for members to better understand how the updated and improved user fee programs will provide FDA with the tools it needs to ensure that patients have timely access to safe and effective new drugs and devices including generics, biosimilars, and others which will increase competition and bring lower cost alternatives to the marketplace.

This subcommittee also examined additional medical device provisions some of which have been updated and are before us today as amendments. I fully support the agreements that are included in this legislation.

Along with Chairman Alexander, we remain committed to a timely reauthorization and let me be clear. 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 also desperately needed treatments and cures will not reach patients. We cannot and we will not let that happen.

I do want to take a moment to thank my colleagues on both sides of the aisle for working on thoughtful ways to improve this legislation. I understand there will be several bipartisan amendments offered today and that there are a host of additional issues that will continue to be discussed and hopefully resolved by our full committee markup. I

appreciate everyone's commitment to better this important bill.

In addition to the FDA Reauthorization Act, we are also considering two public health bills that address two relatively common, but life-threatening diseases. H.R. 2410, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017 sponsored by Representative Danny Davis and Chairman Burgess, reauthorizes the Sickle Cell Disease Treatment Demonstration Program. Sickle Cell Disease is a red blood cell disorder that causes lifelong illness. It is the single most common inherited blood disorder in the United States and still has no cure. Through research, surveillance, prevention and treatment enhanced collaboration with community-based organizations, this bill will lead to better interventions and eventually a cure to this debilitating disease.

Finally, we are considering an amendment in the nature of a substitute to H.R. 1222, the Congenital Heart Failure Reauthorization Act of 2017 by Representative Bilirakis. By improving the CDC's Congenital Heart Disease surveillance system and enhancing biomedical research with respect to congenital heart disease, this legislation will help us better understand and improve long-term outcomes for children and adults with this condition.

So I look forward to advancing these important bills. I would like to thank the entire committee for your dedication into identifying important ways to help our patients and I yield back.

Chairman Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentlelady from Florida, Ms. Castor, for 2 minutes for an opening statement, please.

Ms. Castor. Well, thank you very much, Mr. Chairman. The bills on the agenda today are very positive, bipartisan steps, especially the reauthorization of the way we fund new drug development through user fees. It is very important that we get that done.

But I wanted to note that here we are halfway through the year already. This Health Subcommittee has had nine markups and hearings, but not one on tackling the skyrocketing cost of prescription drugs. And we know there is overwhelming bipartisan support from our neighbors back home, that their representatives here in Washington take action to lower prescription drug costs. In fact, some polls, if you go out and do a little research say that it is the number one issue for our neighbors back home for policy makers in the White House to act on. But you really don't need polls if you listen when you go back home. I am hearing

it and I know my colleagues are as well.

Recent price hikes such as the overnight 5,500 percent increase in the cost of the lifesaving drug Daraprim or the 500 percent increase in the cost of EpiPen, and the $84,000 price tag for the Hepatitis C drug Sovaldi have exposed the injustice in America's drug pricing system. Mr. Chairman, I note that the Senate Health Committee intends to hold a hearing. They said we will schedule a hearing in the near future on drug spending in the U.S. including what we currently spend on drugs, what types of drugs, and what the projections are for drug spending in the future.

This committee should not be derelict. We should take this on and we can tap the expertise from folks all across the country that understand it and begin to draft policy to address the issue and that is my hope and my recommendation to the committee. Thank you and I yield back my time.

Chairman Burgess. The gentlelady yields back. The chair thanks the gentlelady. Does anyone else on the majority side seek recognition? Seeing none, Dr. Schrader, you are recognized for 2 minutes for an opening statement, please.

Mr. Schrader. Thank you very much, Mr. Chairman. I appreciate it. It has been clear that there are a number of things we have disagreed on so far in the committee. I think

that it is nice here today and hopefully in the future to celebrate some of the bipartisan things we do agree on. This FDA user fee legislation that we have in front of us here is just such an opportunity.

Thanks to the bipartisan work, especially by our committee staff and our personnel leg. staff, today we will approve the FDA Reauthorization Act which will ensure timely review of new drug and biologic applications. It will streamline medical device and biosimilar regulations, and it will speed up the review of the generic drug applications, all saving consumers money by ensuring a more smooth regulatory process.

I plan to offer a bipartisan amendment with my colleague, Gus Bilirakis, which will further enhance the generic drug program to spur additional competition in the marketplace, help bring prescription drug costs under control, where bad actors have jacked up these prices dramatically. I will speak more about my amendment when I offer it later, but I wanted to take time to thank my colleague, Mr. Bilirakis, Chairman Walden, Ranking Member Pallone, Chairman Burgess, Ranking Member Green for committing to a nice bipartisan process. It has created some genuinely very good policy and I yield back, Mr. Chairman.

Chairman Burgess. The chair thanks the gentleman and

the gentleman does yield back. Does anyone on the majority side seek time for an opening statement? The chair recognizes the gentlelady from California for 2 minutes for an opening statement.

Ms. Eshoo. Thank you, Mr. Chairman. Good morning, colleagues. Thank you, Mr. Chairman, for holding this subcommittee markup. These are good, bipartisan bills that are before us today and I support them and I thank the authors for the work that they have done on them.

I think that the FDA user fee agreements are really critically important programs because they have provided essential resources to the Agency, (a), and (b), these resources have not only improved the approval processes for medical devices, biosimilars, prescription drugs, and generic drugs, but they have also moved along the time frames for approval which is something that has been a bipartisan priority for this committee and I think our full committee. So I think that it is essential that we pass this legislation. It is must pass and I am very happy that not only the negotiations moved forward, but that it is before us.

I want to thank my colleague, Representative Lance, who has worked with me on another issue. These user fees are 100 percent industry paid private sector dollars and wherever

anyone is on sequestration, those dollars should not be held hostage and so our legislation exempts the user fees from sequestration and I think that that is very important. I hope that we can get rid of sequestration, but wherever that goes, these user fees should not be a part of it. So I thank Representative Lance for that.

I would also like to just raise one issue and that is the biosimilar user fee agreement. I am concerned and I know that we don't want to fool around with the language, but I do want to raise the flag that the issuance for revised or final guidance being pushed back until as late as early 2020 is really upsetting to me to put it mildly. We have been at this since the ACA passed and it just keeps being dragged out, dragged out, dragged out. I think that we can do much better, but I just wanted to raise the flag on it, since I was the House author of that legislation. And I think full implementation is really important to move along the whole issue of biosimilars. So thank you, Mr. Chairman, and I yield back.

Chairman Burgess. The gentlelady yields back. The chair thanks the gentlelady. Does any member on the majority side seek recognition? Seeing none, the chair recognizes the gentlelady from Colorado for 2 minutes for an opening statement.

Ms. DeGette. Thank you, Mr. Chairman. Thank you for bringing up these three important bipartisan bills. I want to commend the committee for looking at the FDA Reauthorization Act because as Mr. Upton said, it builds directly on the 21st Century Cures bill that we worked in such a yeoman's way on this committee last Congress. And it is really exciting to start to see the hard work begin to come to life.

Some of the things that it builds on from Cures are patient-focused drug development, use of real world evidence and biomarker qualification. So I know this is going to be a really important endeavor.

I just want to mention one other issue that is a bipartisan issue that we are hoping to work on this spring and summer. Mr. Latta, Mr. Green, and myself have been collaborating for the last year on another bill that will deliver badly-needed reforms through the approval process for over-the-counter medicines. This bill would modernize how FDA reviews over-the-counter medicines, a process that has not been updated since the 1970s. The current system simply has not kept pace with science, innovation and growth in this over-the-counter market.

Most importantly, the bill takes common-sense steps that will help the FDA prevent and address safety issues rapidly

and efficiently which will be a major benefit for virtually all of our constituents and their families. I wanted to raise this because I think it is really another great promise for improving America's health and I hope as we continue to work to reform FDA review of over-the-counter medicines, we can also talk about this bill. And with that, Mr. Chairman, I yield back.

Chairman Burgess. The gentlelady yields back. The chair thanks the gentlelady. The chair thanks the gentlelady from Illinois, Ms. Schakowsky, 2 minutes for an opening statement, please.

Ms. Schakowsky. Thank you, Mr. Chairman. There are several aspects of this legislation that I fully support. This bill takes important steps to increase the number of generics on the market. For example, it will allow the Food and Drug Administration to hire over a thousand new full-time employees to review generic drug applications. This bill also will provide additional resources for the approval of biosimilars which have the potential of saving between $44 and $250 billion over 10 years compared to biologics. Currently, the FDA has only approved 4 biosimilars, while the European Union has approved 20. So it is critical that we work to get more biosimilars on the market.

However, this bill falls short by doing nothing to truly

reduce the price of prescription drugs. A recent poll found that six in ten Americans believe lowering the price of prescription drugs should be a "top priority" for Congress and President Trump. The president has even said he believes we need to lower drug prices and yet, here we are passing another bill that helps the pharmaceutical industry without a single reform to lower the price of drugs.

The drug pricing crisis cannot be attributed to a single bad actor, or a few block buster drugs. A recent study done by the AARP found that 97 percent of widely used brand name drugs had a price increase that exceeded inflation in 2015. And 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 public insurance programs and ensures that every American can have access to the drugs that they need at an affordable price. Thank you, and I yield back.

Chairman Burgess. The gentlelady yields back. The chair thanks the gentlelady. Seeing no other members seeking to give an opening statement, that concludes opening statements. The chair at this point would call up H.R. 1222 and ask the clerk to report.

[The Bill H.R. 1222 follows:]

606 **********INSERT 1**********

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.

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

For what purpose does the gentleman from Florida seek recognition?

Mr. Bilirakis. Mr. Chairman, I have an amendment in the nature of a substitute at the desk.

[The Amendment offered by Mr. Bilirakis follows:]

**********INSERT 2**********

Chairman Burgess. The clerk will report the amendment.

The Clerk. Amendment in the nature of a substitute to H.R. 1222 offered by Mr. Bilirakis of Florida.

Chairman Burgess. Without objection, the reading of the amendment is dispensed with. The gentleman from Florida is recognized for 5 minutes in support of his amendment.

Mr. Bilirakis. Thank you, Mr. Chairman. My amendment in the nature of a substitute makes minor technical changes based on feedback from HHS.

The Congenital Heart Futures Reauthorization Act would ensure a continued investment in surveillance research to assess the lifelong needs of individuals with congenital heart defects or CHD. These surveillance efforts will help improve our understanding of CHD across the life span from birth to adulthood. This research will help us learn more about demographic factors such as age, race, gender, or ethnicity.

In addition, the legislation emphasizes a need for continued biomedical research at the National Institutes of Health on the diagnosis, treatment, and prevention of CHD. NIH will further research into the causes of congenital heart defects including genetic causes and study long-term outcomes in individuals with CHD of all ages.

NIH may study data collected over a lifetime to identify

effective treatments and outcomes and identify barriers to lifelong care for individuals with congenital heart defects. I was proud to be one of the original authors of this bill when it first was introduced in 2009 with my colleague, Congressman Zack Space, a former member of this committee. I am proud to be able to champion this bipartisan reauthorization bill with my colleague, Congressman Adam Schiff.

This bill has the strong support of the Adult Congenital Heart Association, the Pediatric Congenital Heart Association, The American College of Cardiology, the American Society of Echocardiography, the Society of Thoracic Surgeons, the American Heart Association, and the National Down Syndrome Society, and others as well.

CHD is the most common birth defect and the leading cause of birth defect related infant mortality. It is a true public health issue and as Late Night Show host Jimmy Kimmel noted just a few weeks ago, it does not discriminate by race, gender, or socio-economic status.

The road ahead may be scary and uncertain for any parent with a newborn who has CHD, but this bill helps give hope to those coping with the diagnosis. One in 100 babies are born with CHD and more than 5 percent will not live to see their first birthday. Even for those who receive successful

intervention, it is not a cure. Children and adults born with CHD require on-going, costly, specialized cardiac care and face a lifelong risk of permanent disability and premature death. As a result, healthcare utilization among the CHD population is significantly higher than the general population. It is estimated that compared to their peers, the medical costs for individuals with congenital heart defects are 10 to 20 times greater.

Hospitalization costs for pediatric patients alone total more than $5.6 billion each year which is 15 percent of all hospitalization costs for patients 20 years of age and younger. Despite its prevalence and significance, there are still gaps in research and standards of care for CHD patients.

Previous congressional support of CDC's National Center on Birth Defects and Developmental Disabilities, has yielded an increased understanding of the public health burden of this condition. But for the sake of the estimated 40,000 babies who will be born in the next year with CHD, there is more work to be done.

I ask for the adoption of this amendment in the nature of a substitute and for the swift passage of this bill. I yield back, Mr. Chairman. Thank you.

Chairman Burgess. The chairman thanks the gentleman.

The gentleman yields back. Other discussion on the amendment. For what purpose does the gentlelady from Washington State seek recognition.

Mrs. McMorris Rodgers. Mr. Chairman, I move to strike the last word.

Chairman Burgess. The gentlelady is recognized for 5 minutes.

Mrs. McMorris Rodgers. Thank you, Mr. Chairman, and I want to thank Representative Bilirakis for his work and leadership on this legislation and I speak not just as a fellow colleague, but as a mom. As most of you know, my son or oldest, our son, Cole, was born with that extra 21st chromosome, Down Syndrome, and one of the things about Down Syndrome is that 50 percent of the kids that are diagnosed with Down Syndrome are also born with a hole in their heart, a congenital heart defect, and they immediately have to get surgery. And this legislation is really important and I am excited to support it to provide more research, more surveillance, and hopefully lead to better treatments and long-term outcomes for patients.

I can tell you because of the work that has been done, those with Down Syndrome are living longer than ever. You think about just -- it wasn't that long ago their life expectancy would be 25 to 30 years and now it is 50, 60 years

and it is because of this kind of an effort that we are seeing better outcomes and longer lives. Thank you. I yield back.

Chairman Burgess. The chair thanks the gentlelady. The gentlelady yields back. Is there any other discussion of the amendment? Seeing none, the vote then occurs on the amendment.

All those in favor shall signify by saying aye.

All those opposed nay.

The ayes have it and the amendment is agreed to.

The question now occurs on forwarding H.R. 1222 to the full committee.

All those in favor say aye.

All those opposed say no.

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

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

[The Bill H.R. 2410 follows:]

**********INSERT 3**********

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.

Chairman Burgess. Without objection, the first reading of the bill is dispensed with and the bill be open to amendment at any point. So ordered. Are there any bipartisan amendments to the bill? Are there any amendments to the bill?

The chair will recognize himself to strike the last word to speak on the bill and I recognize myself for 5 minutes.

H.R. 2410, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017 has been introduced by Representative Davis of Illinois and myself. Sickle cell anemia is an inherited disease in which red blood cells are unable to properly carry oxygen throughout the body. The condition causes severe episodes of pain and fatigue and can lead to damage of the eyes and other organs. This important legislation would reauthorize the sickle cell disease treatment demonstration program and enhance the Secretary's ability to conduct surveillance on the epidemiology of sickle cell disease and implement public health initiatives, identify and evaluate sickle cell disease

prevention and treatment strategies.

This bill will move us one step closer to improving the quality of care and symptom management for those affected and I urge support and yield back the balance of my time.

Are there other members seeking recognition on H.R. 2410? Seeing none the question then occurs on the Bill 2410.

All those in favor will say aye.

All those opposed, no.

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

The question now occurs on forwarding H.R. 2410 to the full committee.

All those in favor say aye.

Those opposed no.

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

The chair calls up H.R. 2430 and asks the clerk to report.

[The Bill H.R. 2430 follows:]

**********INSERT 4**********

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 products, and for other purposes.

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

Are there any bipartisan amendments to the bill?

For what purpose does the gentleman from New Jersey seek recognition?

Mr. Pallone. Mr. Chairman, I would just like to strike the last word and speak in support of the bill.

Chairman Burgess. The gentleman is recognized for 5 minutes.

Mr. Pallone. Thank you. Mr. Chairman, the package of user fee agreements before us today represents nearly 2 years of work between the FDA, industry, and other stakeholders. These agreements not only provide FDA with the resources to continue the Agency's critical public health work, but it also provides the medical product industry with certainty and stability in the review process.

The resources provided help the Agency to hire the necessary scientists, investigators, and review staff, as well as undertake new initiatives such as incorporated the

patient perspective into the medical product development and review process, supporting new tools to modernize clinical trials, and improving regulatory science.

Now these agreements certainly do not address every issue that I know members of this committee and other outside stakeholders would like. For example, I mentioned earlier about the drug pricing issue. The vast majority of Republican and Democratic voters all agree that an important healthcare priority for the new president and Congress is making prescription drugs affordable for those that need them and the Government needs to take action to lower drug prices.

However, it is critical that we move the FDA reauthorization swiftly, as we have heard that nearly 5,000 FDA employees would be in danger of being laid off if we don't reauthorize the user fee programs on time.

But I just wanted to touch briefly on some of the key elements of the user fee agreements before us. With regard to PDUFA, the first of the medical product user fee programs, it has been incredibly successful at bringing reviews of new drug applications down by more than half and providing patient access to treatments more quickly, often before any other country. PDUFA VI will maintain current review time tables and will also modernize the user fee structure. The agreement also commits to hiring an additional 230 employees

and builds on the work of 21st Century Cures by investing resources in the development of biomarkers, collection of real world evidence, and supporting innovative clinical trial designs.

Like PDUFA, MDUFA has been successful in bringing medical devices to patients sooner, bringing review times down overall, resulting in the approval of novel, new devices sooner. In fact, just last year, CDRH approved the highest number of novel devices in the history of the MDUFA program, approving 91 novel medical devices. MDUFA IV will build on these successes by advancing the use of the patient perspective and the risk benefit assessment of medical devices, establishing a system called the NEST to utilize real-world data for pre-market approval of new indications and post-market safety monitoring and improving pre-submission communications with sponsors. All of these actions will help to increase the consistency, efficiency, and effectiveness of medical device review.

We are also considering today the reauthorization of two of our newer user fee programs, the generic drug user fee program and the biosimilar user fee program. Both of these programs strive to expedite access to high quality, lower cost drugs for American families and the user fees were meant to help address the interest from sponsors and timely review

of their applications.

Under GDUFA I, FDA worked to address the backlog of generic applications and has committed moving forward in GDUFA II to meeting a 10-month review timetable for traditional applications. GDUFA II also works to help bring generics to market as soon as they are able through improving communications between FDA and sponsors throughout the review process and instituting early communications to aid sponsors in the creation of complex generic drug products. These steps will help to move FDA and sponsors closer towards first cycle approval.

And BSUFA II also builds on the lessons learned under BSUFA I, ensuring that there is sufficient resources and qualified staff to respond to the growing interest in biosimilar development, improving meeting opportunities in order to provide sponsors with meaningful feedback and instituting a similar review model to PDUFA which will allow for greater communications during the review process.

Now I just wanted to note, however, that I was disappointed to receive the letter this week from Secretary Price indicating that this administration would like to recalibrate the user fee agreements. The user fee agreements before us were carefully negotiated by FDA and industry and represent nearly 2 years of deliberations. There are very

real repercussions associated with not passing the reauthorization of these user fee agreements on time. And the reviews of novel medical devices and drugs will come to a halt, thousands of employees will be laid off, and patient access to treatments and medical innovation will be threatened. Very real consequences are on the line. And so again, I urge my colleagues to reject this last-minute plea from the administration. This is a strong bipartisan user fee reauthorization and one that deserves our support. I look forward to continue our work on all of the user fee agreements to ensure they are signed into law as soon as possible.

Thank you, Mr. Chairman. I yield back.

Chairman Burgess. The gentleman yields back. The chair thanks the gentleman. The chair recognizes himself for the purpose of striking the last word. I recognize myself for 5 minutes.

As this committee knows, this subcommittee knows, this bipartisan bills updates and reauthorizes the Food and Drug Administration user fee programs for prescription drugs, for medical devices, for generic drugs and biosimilar, biological products. The Food and Drug Administration Reauthorization Act of 2017 will ensure that the FDA has the tools they need to deliver safe and effective products to patients more

quickly. I think I agree with every member of the subcommittee today that it is important that we do our work and advance the bill out of subcommittee today.

I yield back the balance of my time and ask for any bipartisan amendments.

Mr. Shimkus. I would like to strike the last word.

Chairman Burgess. For what purpose does the gentleman from Illinois seek recognition?

Mr. Shimkus. I would like to strike the last word.

Chairman Burgess. The gentleman is recognized for 5 minutes.

Mr. Shimkus. Thank you, Mr. Chairman. I am very supportive of the whole package. This is probably a unique opportunity to do some add-ons as we have agreed to in the past and I think they have to be bipartisan and I think they have to pass that test of policy writers that will be accepted and move. So in that spirit I want to mention something that I hope we can get some buy in and work on, stuff that we have talked about in other Congresses on the antimicrobial or the "superbug" issue which is a climate that could occur and how do we get a response of antibiotic drugs and remedies to the market as soon as possible. It is something I have worked with Ranking Member Green on and I would hope that we could add this to the package in between

the markup here and the markup to the full committee.

I know just last week, doctors at the University of Illinois at Chicago rang the alarm bells and said Illinois is Ground Zero for the "super bug" cases of the United States and global health experts are sounding the alarm. You can go through the stories. The whole issue is we need to be prepared and administer antibiotics in a large amount as quickly as possible, so the drug companies are being asked to be prepared to prepare something that we hope we never have to use. That is kind of the business debate is that in this case, they have to be able to respond quickly and prepare something and have something on the shelf that we hope we never have to use. So in that vein, I would hope that we can, as in past Congresses, get a chance to work with colleagues like I have with Mr. Green before and add this to the package. I don't think it is controversial in the past. And in fact, FDA has been pretty support of this and Janet Woodcock in her testimony. So with that, I yield to my old friend from Texas.

Mr. Green. I thank my colleague for yielding and thank him for partnering with us over the years. "Super bugs" remain a major issue. Twenty-three thousand Americans die of infections from drug-resistant bacteria for which we have no cure. The pipeline is dry and the threat is grave. Last

user fee reauthorization, we had the GAIN Act. In the 21st Century Cures we had an ADAPT to address some of the regulatory barriers to the antibiotic development. We need robust incentives to address this broken market. Absent new treatments, surgery, neonatal care, chemotherapy, and other medical innovations will be too dangerous to reform.

I want to thank my colleagues, Congressman Shimkus for his partnership and leadership on this and I hope the committee maintains its commitment to addressing the antibiotic resistance crisis because it is a crisis in our country and I look forward to working with you, if not on this bill, on future legislation and thank you for the time. And I yield back.

Chairman Burgess. The chair thanks the gentleman. The gentleman yields back. Does anyone else seek to strike the last word?

Mr. Long. I do.

Chairman Burgess. For what purposes does the gentleman from Missouri seek recognition?

Mr. Long. Mr. Chairman, I would like to strike the last word.

Chairman Burgess. The gentleman is recognized for 5 minutes.

Mr. Long. Thank you, Mr. Chairman. I would simply like

to make a few comments on a piece of legislation we discussed at the recent user fee legislative hearing that is absent from today's markup.

As you know, Representatives Costello and Peters have introduced H.R. 2118, the Medical Device Servicing, Safety, and Accountability Act. This bill would ensure consistency in regulation for proper servicing of medical devices. It is my understanding that the committee is continuing to work the bill with sponsors and stakeholders to improve upon the language.

H.R. 2118 is a practical solution that will protect patients who not only rely on the safety of the medical devices, but also on their effectiveness and reliability. I support its consideration and inclusion when the user fee package comes before the full committee in the near future. Thank you, Mr. Chairman. I yield back.

Chairman Burgess. The gentleman yields back. The chair thanks the gentleman. The bill is open for amendment at any -- I beg your pardon. For what purpose does the gentlelady from California seek recognition.

Ms. Eshoo. I wanted to move to strike the last word, Mr. Chairman.

Chairman Burgess. The gentlelady is recognized for 5 minutes.

Ms. Eshoo. Thank you, Mr. Chairman. I want to express again my support for the registration of third-party servicers who make repairs to medical devices. Although it wasn't discussed today, I am supportive of these efforts to ensure consistency in regulation for proper servicing of medical devices. It is a very important area.

There is currently no oversight of service activities performed by third parties and no registration of those who service medical devices. Third-party servicers are currently not even required to register with the FDA, creating, I think, an enormous blind spot in the very important medical device industry. So I think that this is a serious patient safety issue. There are many third-party servicers who operate safely and effectively as do the devices they service, but without regulation, patients are the ones who really stand to lose the most.

The medical device servicing industry has changed significantly since the issue of device servicing was last seriously considered by the FDA almost 20 years ago. So this has been -- this hasn't been examined for almost 2 decades. I think that the proposal that we have that is currently being finalized is going to bring transparency and consistency to FDA's oversight of third party medical device service companies without adding an undue burden to the

companies.

So I think it is a common sense approach that will improve patient safety and proper maintenance of lifesaving medical technology and that the proposal, I think, is a practical solution. It is going to protect patients who not only rely on the safety of medical device technologies, but also very importantly their effectiveness and reliability.

So I look forward to discussing the proposal that both Representatives Costello and Peters will raise during our full committee markup, but I did want to make some comments on it today. And I thank you, Mr. Chairman, and I yield back.

Chairman Burgess. The chair thanks the gentlelady. The gentlelady yields back. Other members seeking recognition of bipartisan amendments? For what purpose does the gentleman from Massachusetts seek recognition?

Mr. Kennedy. Thank you, Mr. Chairman. I have an amendment at the desk.

[The Amendment offered by Mr. Kennedy follows:]

**********COMMITTEE INSERT 1**********

Chairman Burgess. The clerk will report the amendment.

The Clerk. Amendment offered by Mr. Kennedy.

Chairman Burgess. Without objection, the reading of the amendment is dispensed with and the gentleman is recognized for 5 minutes in support of his amendment.

Mr. Kennedy. Thank you, Mr. Chairman. I want to thank you and Ranking Member Green for holding this markup today and for all of your work on the user fee agreement. Passing robust user fee legislation must be a priority and I am pleased to see a bipartisan draft before us today. I cannot understate the importance of reliable FDA when it comes to many life sciences businesses that call Massachusetts home

and my district as well.

I would also like to thank Representative Blackburn and her staff for all of the work that they have done to help those individuals with hearing loss to get easier access to affordable and safe care.

The amendment that I am offering this morning would create a category of over-the-counter hearing aids at the FDA. Currently, Medicare does not cover the cost of hearing aids which can exceed $2,000 per ear.

Additionally, according to AARP, roughly 40 percent of the over 60 population experiences hearing loss, yet only about 20 percent of those affected use a hearing aid. Affordability and accessibility are some of the biggest barriers to getting hearing aids. That is why Congresswoman Blackburn and I introduced the bipartisan legislation and why it already has support of consumers, doctors, industry, and AARP.

With innovation taking place in our districts and increased competition among businesses, it can improve the quality of hearing aids, protect patients, while simultaneously lowering costs. According to the FDA, over-the-counter hearing aids will provide "a more flexible approach to hear aid regulation which has the potential to deliver new, innovative, and lower cost products to millions

of consumers, while ensuring proper safeguards that will protect patients."

With the FDA's assurance of safety and efficacy, with clear labeling, and with the proper volume output limits, these devices will be able to safely address hearing loss for millions of Americans who simply forego care in the current market.

As the process to reauthorize the user fee bill continues in the coming days and weeks, I look forward to addressing any outstanding concerns and to working with my colleagues on both sides of the aisle to perfect the language. I urge everyone to support this amendment and Mr. Chairman, I have a piece that I would like to submit for the record of FDA technical assistance, if I may, and I would yield my time to whoever would like it.

Chairman Burgess. Without objection, so ordered. It will be added to the record.

Mr. Kennedy. I happily yield to Ms. Blackburn.

Ms. Blackburn. Thank you, Mr. Chairman. And I am so pleased to join Mr. Kennedy in this amendment. And in making this something that is available for our constituents.

I think it is important to note that under current regulations dating back to the '70s, only 20 percent of Americans who could benefit from hearing aids actually end up

getting one. And as we heard in the subcommittee hearing earlier this month, the primary reason for the low rate of utilization and adoption includes the high cost of hearing aids which is over $4,000 per pair and it is a stigma and then you have the cost and then difficulty accessing it.

Now Mr. Kennedy mentioned different people that have supported making this change. You have PCAST, you have the National Academies of Science, Engineering, and Medicine have recommended that the time has come for consumers to be able to access hearing aid products over the counter for treatment of mild and moderate hearing loss.

The bill addresses each of the key reasons identified by experts for the low utilization of hearing aids. And over-the-counter hearing aid regulated as safe and effective by the FDA would cost hundreds of dollars, not thousands of dollars. By allowing those with mild and moderate hearing loss to directly access and self-fit hearing aids, we will encourage many of those who just wouldn't participate in today's hearing aid system to seek and to get help.

I am really grateful that we have so many audiologists who support this bill, including the Academy of Doctors of Audiology and as Mr. Kennedy mentioned, the list of supporters of this legislation is growing. It includes the Consumer Technology Association, the American Association of Retired

Persons, among many others, and I encourage our colleagues to support this amendment and I yield back.

Chairman Burgess. The chair thanks the gentlelady. Does the gentleman yield back the balance of the time? The chair would recognize himself for 5 minutes for the purpose of striking the last word.

I have observed that untreated hearing loss is not a benign condition, even mild to moderate impairments in hearing can result in impairments to the quality of life. FDA regulations have not kept pace with the rapid advancements in hearing aid technologies, so access to hearing aids has remained a significant barrier to millions of Americans from whom they would benefit.

This amendment before us today is based on H.R. 1652 authored by Mr. Kennedy and Ms. Blackburn. By directing the Food and Drug Administration to establish a category of over-the-counter hearing aids, Americans with mild to moderate hearing loss will benefit from life changing and in some cases, life saving hearing technologies at competitive prices.

At a hearing of this subcommittee several weeks ago, Dr. Jeffrey Shuren from the Food and Drug Administration, Dr. Frank Lin, the Johns Hopkins ear, nose, and throat physician, and a leading expert on hearing loss, unequivocally agreed with the conclusions of the President's Council of Advisors on

Science and Technology and the National Academies of Science, Engineering, and Medicine, an NIH-funded peer reviewed, placebo control study that a category of OTC hearing aids would be safe and effective for adults with mild to moderate hearing loss.

Dr. Shuren and Dr. Lin also testified that there is no scientific, nor any medical basis, to justify medical screening as a condition of purchasing an over-the-counter hearing aid since the likelihood of detecting a serious, treatable condition is minute, but the burden of such a requirement could be a significant barrier to access for consumers.

Furthermore, the legislation does require the Food and Drug Administration to establish safe output limits and safety labeling to protect children and those with other serious ear conditions. I urge my colleagues to join me in supporting this bipartisan, bicameral effort to greatly improve the lives of Americans who are hearing impaired. And I will yield back the balance of my time. Do any other members seek recognition?

For what purpose does the gentlelady from California seek recognition?

Ms. Matsui. Mr. Chairman, I move to strike the last word.

Chairman Burgess. The gentlelady is recognized for 5 minutes.

Ms. Matsui. As with my colleague on the other side of the aisle, Representative Guthrie of the Early Hearing Detection and Intervention authorization bill to ensure babies are screened for hearing loss, I am very interested in ensuring that infants and children with hearing loss are given every opportunity to learn, grow, and thrive. And on the other end of the spectrum, I am also concerned about the impact of an availability of hearing aids for older Americans. I know that barriers currently exist for seniors to obtain hearing aids, including a sometime significant cost barrier which Representatives Kennedy and Blackburn amendment before us intends to address.

I am hopeful that if the FDA moves forward to create an over-the-counter market for hearing aids, we can all work together to ensure there are no unintended negative consequences for consumers. For example, we should require that the label on over-the-counter hearing aids indicates that the product is not meant for use in children. We should also ensure that there is adequate surveillance, evaluation, and communication as the over-the-counter market is created so that we have a feedback loop to catch any problems.

I do look forward to continue to work with my colleagues

as this bill advances. I believe this is really a wonderful step forward. Thank you and I yield to anyone who wishes. I yield back.

Chairman Burgess. The chair thanks the gentlelady. The gentlelady yields back. Other discussion of the amendment? If there is no further discussion, the vote occurs on the amendment.

All those in favor shall signify by saying aye.

All those opposed nay.

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

Are there further bipartisan amendments to the bill?

Mr. Bucshon. Mr. Chairman.

Chairman Burgess. For what purpose does the gentleman from Indiana seek recognition?

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

[The Amendment offered by Mr. Smith follows:]

**********COMMITTEE INSERT 2**********

Chairman Burgess. The clerk will report the amendment. Clerk will suspend. The chair failed to mention that the amendment was agreed to and will be reported. Now we will proceed with the reporting of the gentleman from Indiana's amendment.

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

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

Mr. Bucshon. Thank you, Mr. Chairman. This amendment contains the text of H.R. 1736 with FDA technical assistance changes. It seeks to improve the quality and efficiency of the inspection process for medical technology manufacturers by applying a transparent and risk-based approach to the frequency and nature of device establishment inspections, allowing FDA to focus its resources where they are needed most and reducing the regulatory burden on establishments with a strong history of compliance.

This amendment also improves the communications process between the FDA and manufacturers to provide more consistency and certainty for device establishments.

I would like to thank Ms. Brooks, Mr. Butterfield, and Mr. Peters for their leadership on this amendment. I urge my

colleagues to support this amendment and I look forward to moving this legislation through the subcommittee, the committee, and to the House floor and I yield back the balance of my time.

Chairman Burgess. The chair thanks the gentleman. The gentleman yields back. For what purpose does the gentleman from North Carolina seek recognition?

Mr. Butterfield. I move to strike the last word.

Chairman Burgess. The gentleman is recognized for 5 minutes.

Mr. Butterfield. Thank you, Mr. Chairman. Mr. Chairman, I am proud today to offer this amendment along with my colleague, Mr. Bucshon. It is a common sense, bipartisan amendment that will improve patient safety by ensuring that the FDA is making the best use of its resources. And it will provide some much needed consistency and transparency in routine inspections process.

I have heard from many companies in my state and from other states that there are vast discrepancies of inspections between facilities across districts in the United States as well as between facilities of the same company within the U.S. and outside of the U.S. These discrepancies result in facilities being held to different standards simply because of where they are located and to Mr. Bucshon and myself and

others, this makes no sense.

Of course, we want FDA to conduct rigorous inspections and this amendment does not change their authority to do that. But we also want FDA to be consistent in their approach and the heart of this amendment addresses those issues. This amendment, Mr. Chairman, will provide some much-needed consistency and transparency into the routine inspections process by establishing some rules of the road for the FDA inspectors, as they inspect device facilities like regular communications between FDA inspectors and the facility, both before, during, and after the inspection.

As I said before, nothing in this bill takes away or limits FDA's ability to inspect. Instead, it directs FDA to focus its inspection resources on the more significant risk to public health and establishes these important process improvements that I just mentioned.

We have heard from the FDA at two hearings now that this is a good policy and that they agree that this proposal puts forward needed changes to complement what FDA is already doing in this space. And so I am proud to work with my colleagues from both sides of the aisle on this amendment. I urge my colleagues to join with me in voting for it.

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

Chairman Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes himself for purposes of striking the last word.

Mrs. Brooks. Mr. Chairman, I move to strike the last word.

Chairman Burgess. For what purpose does the gentlelady from Indiana seek recognition?

Mrs. Brooks. Move to strike the last word.

Chairman Burgess. The gentlelady is recognized for 5 minutes.

Mrs. Brooks. Mr. Chairman, I, too, would like to voice my support for the amendment offered by my colleague from Indiana, Dr. Bucshon. Consistency is the word of the day with this bill and this amendment is a good-faith effort by Congress, the FDA, and the medical device industry to bring much-needed consistency of the inspections process.

Why is a standardized inspections process important? Let me give you an example. Following an inspection, companies must respond to the FDA within 15 days with a full remediation plan. However, the FDA is under no obligation to respond to this plan. Therefore, companies are left in the dark, sometimes until after the next inspection. They don't know whether or not the changes they are making meet the FDA standards and won't until their next inspection.

This amendment is about making sure that the FDA responds in a timely way to companies' remediation plans so companies can move forward with their fixes. This amendment ensures the FDA inspectors and companies have clear parameters for communications before, during, and after inspections and provides much needed guidance for both parties involved.

I would like to thank my colleagues, Dr. Bucshon, Congressman Peters, Congressman Butterfield, and the Energy and Commerce staff for their hard work. I urge my colleagues to support this amendment and I yield back.

Chairman Burgess. The chair thanks the gentlelady. The gentlelady yields back. Further discussion on the amendment? If there is no further discussion, the vote will occur on the amendment.

All those in favor shall signify by saying aye.

Those opposed nay.

The ayes have it and the amendment is agreed to.

Are there further amendments on the bill? The chair will recognize himself for the purpose of offering an amendment. I have an amendment at the desk.

[The Amendment offered by Mr. Burgess follows:]

**********COMMITTEE INSERT 3**********

1354 The Clerk. Amendment to H.R. 2430 offered by Mr.
1355 Burgess.
1356 Chairman Burgess. Without objection, the reading of the
1357 amendment is dispensed with and I will recognize myself for 5
1358 minutes.
1359 This amendment is identical to a bill introduced by
1360 Representatives Lance, Dingell, Green, and myself, H.R. 2376,
1361 the Drug Diversion and Counterfeit Crackdown Act of 2017.
1362 This bill is narrowly tailored to close certain gaps and
1363 inconsistencies in existing law that are intended to keep
1364 counterfeit and diverted drugs out of our nation's healthcare
1365 system.
1366 Under current law, the penalties for illegally diverting
1367 drugs into the United States that were manufactured abroad and
1368 intended for foreign markets are significantly less than if
1369 the drugs were initially manufactured in the United States.
1370 Further, the penalties for counterfeiting are much lower than
1371 for diversion. There is no public health or patient safety
1372 rationale for these arbitrary distinctions.
1373 The Drug Diversion and Counterfeit Crackdown Act of 2017
1374 would make two minor changes to the Federal Food, Drug and
1375 Cosmetic Act. First, it would provide the same penalties for
1376 diverting drugs made outside the United States and intended
1377 for a foreign market as the penalties that currently exist are

diverting drugs made inside the United States and intended for a foreign market.

Second, it would also increase the penalties for counterfeiting to match the current penalties for diversion. Absent a penalty structure, the law threatens our drug supply chain, creating potential harm to public health by failing to appropriately penalize the sale or distribution of counterfeit and diverted drugs. This amendment will make minor additions to the statute to close these loopholes protecting consumers.

And I would like to yield to the ranking member of the subcommittee, Mr. Green, for his comments.

Mr. Green. Thank you, Mr. Chairman, for yielding to me. This amendment strengthens the drug supply chain security by aligning the penalties for counterfeit and diverted drugs. It simply clarifies that prescription drugs manufactured and labeled for non-U.S. markets shall not be diverted into the U.S. unless legally imported by the individuals or in a shortage situation and increases the penalties for counterfeit drugs.

Patient safety is tantamount and this amendment is a step towards better protection. This committee took huge strides when we enacted the track and trace legislation. Our amendment builds on this success to further protect and strengthen our drug supply chain security. And thank you for

yielding to me. I yield back.

Chairman Burgess. The chair thanks the gentleman. The chair yields back. For what purpose does the gentleman from New Jersey seek recognition?

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

Chairman Burgess. The gentleman is recognized for 5 minutes.

Mr. Lance. I am proud to join you, Chairman Burgess and Mr. Green, in support of this amendment that will crack down on counterfeit drugs that enter the United States. Too many American patients are given counterfeit and adulterated drugs disguised as reputable brands and this amendment will increase the penalties for counterfeiters. Counterfeit drugs are coming into the United States and Americans are falling victims to knockoffs that have infiltrated the U.S. supply chain. These counterfeit drugs may contain harmful ingredients and incorrect or expired active ingredients. Criminals take the risk knowing that the punishment is a minor offense in our criminal code. That needs to change. We need to strengthen the system and protect patients.

To reach the market, a new drug must proceed through the vigorous vetting process at the FDA. Once approved, these therapies are then marketed in the United States.

Counterfeiters mimic these drugs with medications often manufactured in Third World countries, well outside the scrutiny of the FDA and involving a host of ingredients that are harmful.

The Centers for Disease Control estimates that up to 30 percent of all drugs in developing countries are counterfeits. Our legislative work on this will close loopholes in the law, stiffen penalties for counterfeiters, and discourage this market from growing.

On a brief, unrelated note, Mr. Chairman, my thanks to you for the work the committee has done and the outreach that Representatives Costello and Peters have done to me and my office related to their third party servicing bill. I hope that this is an issue the committee will continue to include in the final user fee package.

Thank you, Mr. Chairman, for your support of this important amendment that will protect the safety of the American people and to Mr. Green as well, and I yield back the balance of my time.

Chairman Burgess. The gentleman yields back. The chair thanks the gentleman. Other discussion? For what purpose does the gentleman from California seek recognition?

Mr. Cardenas. Request to strike the last word.

Chairman Burgess. The gentleman is recognized for 5

minutes.

Mr. Cardenas. Thank you very much, Mr. Chairman. I think it is important for everybody, for our constituents to understand how serious this matter is. This matter and I would like to thank the authors for this measure, is in the tens of billions of dollars a year. This is not some haphazard once in a while issue. This affects Americans of every age and unfortunately, what happens in certain communities where to save a couple of dollars, they end up going to a market where they end up getting something that on the surface looks like it is what they need and they think they are getting what they need for their health. In reality, what they are getting is something that could, in fact, harm them or even kill them.

So the magnitude of this issue is tremendous and I think that we need to continue with this measure and any measures to make sure that we close this horrendous act that actually in the end does, in fact, take people's lives. So I would like to thank the authors.

Ms. DeGette. Will the gentleman yield?

Mr. Cardenas. Yes, I will yield.

Ms. DeGette. I just want to underscore that. Some years ago, we had a series of hearings in the Oversight and Investigation Subcommittee about the tremendous pressures that

counterfeit drugs are putting on our entry sites into the U.S. and how when people are ordering these drugs, they have no idea. It is not just counterfeit drugs, but it is also the way they are handled in transit and so many other issues. We really do need to work very closely to get a grip on this. I think this amendment is a good first step. I thank the gentleman for yielding.

Chairman Burgess. The gentleman yields back. The chair thanks the gentleman. For what purpose does the gentleman from Kentucky seek recognition?

Mr. Guthrie. I move to strike the last word.

Chairman Burgess. The gentleman is recognized for 5 minutes.

Mr. Guthrie. Thank you, Mr. Chairman. I would like to strike the last word to speak about my bill, H.R. 2026, the Pharmaceutical Information and Exchange Act of 2017.

Earlier this year, the FDA released a draft guidance to enable greater post-approval communication of healthcare economic information between medical and product manufacturers and help decision makers such as health plans and integrated delivery networks.

The FDA guidance was 20 years in the making and this committee passed the law in 1997 to create a safe harbor for this communication, but FDA never released guidance of

industry on how the agency would interpret the law. FDA's issuance of a draft guidance in January is a welcome step in the right direction, but it leaves several issues unresolved that warrant targeted clarifications in the statute.

My bill would enable greater information exchange in order to guide health plans, pharmacy benefit managers, and others who develop prescription drug formularies and help them make well-informed decisions about the benefits and costs of medications for the populations they cover.

Patients benefit when these formulary decisions are informed by the most recent and reliable scientific evidence on drugs, beyond just what was learned from the clinical trials conducted for FDA approval.

Our committee has addressed post-approval information exchange. We should take the next logical step by addressing what information can and should be exchanged pre-approval by considering H.R. 2026. That draft FDA guidance from January also includes a helpful first step towards creating a safe harbor for pre-approval communications in the sharing of information between manufacturers and payers. However, the draft guidance remains non-binding. If our experience with post-approval communications taught us anything, it is that we need both a law to establish the principle and guidance to interpret and clarify the details. Without a legislative safe

harbor, corporations are going to avoid this area to ensure they don't violate the current prohibitions against pre-approval promotion of medical products.

Pre-approval information exchange is important to manufacturers, payers, and integrated healthcare delivery networks because it will increase a utilization of value-based pharmaceutical payment models. It will also allow payers to forecast and budget more accurately for their pharmaceutical spend instead of being surprised by mid-year breakthrough drugs like the recent advances in Hepatitis C treatment.

I hope my colleagues will take a look at my bill, H.R. 2026, the Pharmaceutical Information Exchange Act of 2017 and I invite anyone who is interested in sitting down and working through outstanding questions or concerns they might have before the full committee markup.

I would also like to submit for the record a letter dated April 19th that was submitted to the FDA in response to their draft guidance document. The letter supports the approach taken at H.R. 2026. The letter was signed by a wide variety of organizations including health systems, payers, PBMs, and pharmaceutical manufacturers. I have the letter to submit.

Chairman Burgess. Without objection, so ordered.

Mr. Guthrie. And I would like to yield to the chairman of the full committee, Mr. Walden.

The Chairman. I thank the gentleman from Kentucky for his work on H.R. 2026, the Pharmaceutical Information Exchange Act. Last year in 21st Century Cures Act, our committee took important strides to ensure that better information sharing between the innovators who discovered new treatments and the payers that provider access to patients. We think this is important.

However, more work is needed to modernize the FDA regulations that needlessly restrict and hamper the sharing of clinical and health economic information. Decisions that payers make regarding coverage and formulary placement are critical in ensuring the right patient is getting the right drug for the right value. These decision makers have stated that waiting for FDA approval needlessly delays and blocks access to important clinical and economic data to inform their judgment.

As noted by the Academy of Managed Care Pharmacy, and I quote, "Access to this information is needed 12 to 18 months before FDA approval when organizations are deciding on terms of coverage and budgetary assumptions for state health insurance rates filings, Medicare and Medicaid bids and contracts with healthcare purchasers and other financial arrangements."

Federal law and regulations are not allowing this

1570 important exchange of information to occur. There is simply
1571 no good reason we should continue the status quo.
1572 Your bill, Mr. Guthrie, is a good step toward addressing
1573 this glaring problem. I believe it is something we need to
1574 move forward on. A broad array of managed care plans helps
1575 systems, biopharma innovators, economists and academia.
1576 Backing your effort is a strong indication that you put
1577 forward a good idea whose time has come. Our laws must be
1578 updated to ensure the right patient is getting the right
1579 treatment for the right value. I yield back.
1580 Chairman Burgess. The gentleman yields back. The chair
1581 thanks the gentleman. Are there other members seeking
1582 discussion of the amendment? For what purposes does the
1583 gentleman from Virginia seek recognition?
1584 Mr. Griffith. Mr. Chairman, strike the last word.
1585 Chairman Burgess. The gentleman is recognized for 5
1586 minutes.
1587 Mr. Griffith. Thank you, Chairman Burgess. This is a
1588 good amendment, but I would like to take this time to discuss
1589 a collateral issue that you know well, both in your previous
1590 life as a practicing physician and in your current role as a
1591 legislator. The long overdue need for Congress to clarify how
1592 medical product manufacturers can responsibly engage in a
1593 meaningful dialogue about data and information that is not

included in their product labeling.

When FDA approves a drug or device, it is authorizing the manufacturer to market the product for certain uses or in specific manners that are included in the label. While manufacturers cannot promote or advertise their product for off-label uses, doctors prescribe and administer drugs and devices based on their medical expertise and information they have gathered from a variety of sources that are not limited to the FDA-approved labeling. Oftentimes the information contained in the labeling is vastly different than the accepted uses of the product in clinical practice. We have heard time and time again that a large percentage of cancer, rare disease and pediatric patients receive off-label treatments as the standard of care. In fact, estimates suggest that around 40 percent of overall prescribing decisions are off label.

Product manufacturers often have data and scientific findings that would inform physicians as they are determining the best course of treatment for their patients. However, not only has the FDA strictly prohibited companies from proactively disseminating such information with the threat of criminal penalties and multi-billion dollar fines attached, the agency has recently made the case that the companies' mere knowledge that one of their products is being used off label

could constitute evidence to be used against them in a court of law.

Starting around 2011, the legal landscape began to dramatically shift. There have been a number of court decisions that raise significant first amendment questions about the FDA's authority to restrict a drug or device manufacturer from communicating truthful and non-misleading off-label information about their products.

Regardless of what one may think with the outcomes of these decisions, the bottom line is that the judiciary branch has become the de facto policy makers due to our inaction. I would argue that federal judges and their clerks have a less nuanced understanding and appreciation for the FDA approval process than does this committee.

Congress needs to step up to the plate and responsibly set the rules of the road before it is too late which is why I introduced H.R. 1703, the Medical Product Communications Act. This is not a bill about television ads or snake oil salesmen. This is a good-faith attempt to ensure that companies who often have the most accurate and up-to-date information about their products can provide doctors and researchers with that information and in the appropriate context to improve patient care and facilitate additional research.

I have letters here from over a dozen rare disease

patient advocacy groups as well as the Healthcare Leadership Council expressing strong support for H.R. 1703. I would like to insert those into the record.

Chairman Burgess. Without objection, so ordered.

Mr. Griffith. I also have a letter that sent to the FDA by the Arthritis Foundation, the Cancer Support Community, the Leukemia and Lymphoma Society, the Lupus Foundation of America, the Musella Foundation for Brain Tumor Research, the National Alliance on Mental Illness, the National Organization for Rare Diseases and the Oncology Nursing Society. This letter states: "The current restrictions on communications of off-label information may be intended to protect patient safety, but in certain cases it limits the ability of many patients to learn about, understand, and access vital treatments and therapies. There must be more flexibility and opportunities to proactively share clinical and research findings from diverse sources beyond the label." I agree.

Again, I believe H.R. 1703 responsibly clarifies some key terms and concepts of the statute, interpretations and applications which have stifled constitutionally-protected and medically-valuable information from being shared. I am open to any and all suggestions from my colleagues on both sides of the aisle about how we can improve this legislation, however, doing nothing is no longer an option.

And Mr. Chairman, I would then yield to you.

Chairman Burgess. Thank you, Mr. Griffith. I feel you are correct. I have been following this issue closely for some time. In the past, I have offered solutions that some might say go a bit farther than H.R. 1703. This is a very thoughtful approach and I certainly thank you for your leadership on there. Restricting accurate and up-to-date information from reaching healthcare providers is not only constitutionally suspect, but it is bad public health policy and I would like to yield to the chairman of the full committee, Mr. Walden.

The Chairman. I thank the gentleman and I would like to second Dr. Burgess' appreciation. This is something the committee should clarify legislatively. I am open to any constructive feedback from all members to improve this bill and find bipartisan consensus. Simply put, federal law and regulation is not kept up with how medicine is being practiced today and the court should not be the ones deciding these matters for us. And so thank you for your work and I yield back.

Chairman Burgess. The chair thanks the gentleman. The gentleman yields back. Is there further discussion of the amendment? If there is no further discussion --

Mr. Mullin. I don't know if I'm supposed to strike the

last word now or next.

Chairman Burgess. For what purpose does the gentleman from Oklahoma seek recognition?

Mr. Mullin. I would like to move to strike the last word, please.

Chairman Burgess. The gentleman is recognized for 5 minutes.

Mr. Mullin. Thank you, Mr. Chairman. I want to talk a little bit about a bill that is near and dear to my heart. It is called the RACE for Children Act. An Oklahoma family very recently lost their two-year-old son, Kai McAlpin. Earlier this year, Kai died of pediatric cancer. His family, his parents who I have got to know very well referred to Kai as Kai Warrior.

Clinical trial research for children with cancer lags behind the adult cancer research for many years, so even though there are breakthroughs in cancer research and treatment for adult cancer, children like Kai won't reap any of those benefits.

The RACE for Children Act would address the lack of access pediatric cancer research has in novel and promising clinical trials that they have been proven to show in adults. I would like to thank my colleagues, Chairman McCaul and Chairman Butterfield for introducing the RACE for Children

Act. I look forward to working with my colleagues on this committee and I want to continue to work to pass a RACE for Children Act.

Hopefully, life saving cancer treatments can be made available to these children. I would like to yield some time to Chairman Butterfield and then I will take the time back.

Mr. Butterfield. Thank you to my friend, Representative Mullin, and thank you for promoting me to chairman. I am going to decline that --

Mr. Mullin. I am sorry about that. I was just reading what was on my paper.

Mr. Butterfield. But thank you for your advocacy on this issue, Mr. Mullin. It is very appropriate. Five years ago, Mr. Chairman, 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 so I am proud to say that Congress passed the Creating Hope Act in 2012 as part of the last PDUFA agreement. I am also proud to report that last year as part of the 21st Century Cures Act, Congress reauthorized the pediatric PRV program. The PRV program has transformed the development of drugs expressly for children by creating almost $1 billion in voucher sales.

However, besides drugs developed expressly for children, there are also many, many, many drugs developed for adults that could benefit children. In fact, there are almost 900 drugs, Mr. Chairman, in the adult cancer pipeline. However, only a handful are in development for children. with cancer. This is an opportunity. This science, if the science is available to find better cures for adults, why can't we also apply these cures for children?

In fact, there is a law, the Pediatric Research Equity Act that requires companies developing adult drugs to also undertake studies of their drugs in children. Since Congress passed the bill in 2003, it has been very valuable. It has been a valuable program and has resulted in pediatric studies of 456 drugs. However, drugs for cancer, the number one disease killer of children are excused from PREA, pediatric studies because of two loopholes.

It is imperative that this committee and the House act to pass my bill that I introduced with Chairman Mike McCaul called the Research to Accelerate Cures and Equity for Children Act, the RACE for Children Act, to close these loopholes and ensure that the protection of the Pediatric Research Equity Act are extended to children with cancer.

I am sorry that we cannot adopt the RACE for Children Act today, but there is more work to be done in developing

specific and widely supported language for this critical act. And so I want you, Mr. Burgess, and Mr. Pallone, if you will so kindly, that we work with our Senate colleagues and the committee staff and advocates in this regard.

To that end, I ask you for a commitment, sir, to work with me, to work with Mr. Mullin and the bill's sponsors as this process moves forward so we can deliver results sooner rather than later for vulnerable populations of the benefit from life-saving treatments. I now yield the remainder of my time to my respected chairman, Mr. Burgess.

Chairman Burgess. And the chair thanks you for yielding and thanks Congressman Mullin and you for your work with Representative McCaul on this important initiative.

This subcommittee has a long and rich history of commitment to incentivizing and speeding medical innovation and both Chairman Walden and I are dedicated to working with you on this legislation between now and the full committee markup.

There is no cause more worthy than increasing the number of safe and effective treatments available to children battling cancer and I assure you we are dedicated to advancing that policy and will do so. I yield back to Mr. Mullin who I suspect is yielding back the balance of the time.

Mr. Mullin. I will yield back my time.

Chairman Burgess. The chair thanks the gentleman for yielding back the balance of the time. The gentlelady is recognized for 5 minutes.

Ms. Eshoo. Thank you, Mr. Chairman. I appreciate the issue that we are talking about right now and I appreciate the good words that my friend that just spoke offered about both the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, both the BPCA and PREA.

I am proud to be the author of both of those bills and I am especially proud they were bipartisan, of course. I am especially proud of how successful the programs have been in treating children resulting in new dosing information, new indications of use, new safety information, and new data on effectiveness.

These programs really recognize that children are not just small adults. They have unique medical needs and drugs react differently in their very small bodies. Before both of these pieces of legislation became law, the vast majority of drugs, more than 80 percent used in children, were used off label without data for their safety and efficacy. Today, that number has been reduced to 50 percent. So we are making progress and I am pleased that both of these programs were permanently reauthorized through the last user fee agreements in 2012.

There is always room to make improvements in anything that we have done. And I stand to work with those that are working to improve it. I think that as we move forward, we want to make sure that the FDA reauthorization moves through very smoothly and I also understand that conversations about reforms are ongoing and were not ready for this subcommittee's markup, but I think the user fee agreements present an opportunity.

So to Mr. Butterfield and to others, I stand ready to work with you and I want to encourage all of the stakeholders to do what is best to improve the quality and the quantity of life saving pharmaceutical therapies that are available to children and my commitment is there. And I think both of the laws speak for themselves in terms of having accomplished that.

So I look forward to working with members of the committee, the staff, certainly the Senate, on this issue and I yield back.

Chairman Burgess. The gentlelady yields back. The chair thanks the gentlelady. Is there further discussion of the amendment? If there is no further discussion, the vote occurs on the amendment.

All those in favor shall signify by saying aye.

All those opposed nay.

The ayes have it and the amendment is agreed to.

Are there further amendments to the bill? For what purpose does the gentleman from Oregon seek recognition?

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

[The Amendment offered by Mr. Schrader follows:]

**********COMMITTEE INSERT 4**********

Chairman Burgess. The clerk will report the amendment.

The Clerk. Amendment to H.R. 2430 offered by Mr. Schrader of Oregon.

Chairman Burgess. Without objection, the reading of the amendment is dispensed with and the gentleman is recognized for 5 minutes in support of the amendment.

Mr. Schrader. Thank you very much, Mr. Chairman. Last year, a constituent of mine named Susan contacted my office in dismay. Syprine, a drug she took for a rare disease, had risen in price from $600 a month to $22,000 a month, over a very short period of time. The drug wasn't innovative. It wasn't new. In fact, it was off patent. It had first been approved by the FDA in 1985.

So what changed? It wasn't the drug's formulation, the cost of ingredients, or even a shortage of supply. The only thing that changed was Valeant, the manufacturer of this prescription drug, decided to raise the price, raise it again, and again and again, before long leaving Susan in her own words hopeless. There was no generic competitor for this drug and she couldn't continue to afford that life-saving medication.

Unfortunately, this is not the first time we have heard a story like this. We all heard about Martin Shkreli at Turing who raised the price of Daraprim, another critical life-saving

drug for those with a rare disease, over 5,000 percent overnight, overnight. Again, no generic competition for this drug. Nothing to force the price to come down.

We have all known for a time now this is an area that Congress need to act to ensure these abuses would not continue. I decided last year to work across the aisle with my good friend, Gus Bilirakis, to combat this problem and work to encourage generic competition where there isn't any in the market.

We know that when generic drugs compete in the market, drug prices come down dramatically. Although nine out of ten prescriptions are for generic medications, generic drugs make up only 28 percent of the total cost of prescription drug spending.

Unfortunately though some drugs for small patient populations may not attract the same interest from generic drug manufacturers due to market and regulatory uncertainty. This amendment takes many steps to encourage competition and lower prices here today.

First, the amendment requires greater communication between the FDA and manufacturers for these competitive generic products before and during the application process. We have seen great strides for faster drug approvals in the brand drug breakthrough process. And this is modeled after

that.

The base bill also puts the application on the accelerated review process time line, bringing it to market quicker and cutting into any anticipated exorbitant profit margins, unscrupulous actors plan to reap, and discouraging bad actors' behavior in the first place.

The amendment also creates an incentive for this select set of particular generic drugs to come to market by guaranteeing them the same 6 months of exclusivity that the vast majority of first generic drugs currently receive. Under current law, generic drugs challenging a patented drug, they get this treatment. This would extend that treatment for new generic drugs competing with off-patent brand drugs where there is no competition.

The amendment also closes a loophole and improves program integrity in the tropical disease priority review voucher program more consistent with legislative intent, ensures greater transparency at the FDA, and studies what we can do about getting more first-cycle approvals in the generic drug review program.

There is no doubt there is a lot more we can do to reduce drug prices going forward and we have heard that here today. This amendment takes great steps to work quickly bringing more generic competition to the market which can bring prices down

dramatically.

Again, I would like to thank my good friend, Mr. Bilirakis, and the committee leadership for their work on this amendment and I urge my colleagues to support it. With that, I yield back, Mr. Chairman.

Chairman Burgess. The chair thanks the gentleman. The gentleman yields back. For what purpose does the gentleman from Florida seek recognition?

Mr. Bilirakis. I ask to strike the last word, Mr. Chairman.

Chairman Burgess. The gentleman is recognized for 5 minutes.

Mr. Bilirakis. I appreciate it. I appreciate the committee taking up this amendment based on the bipartisan Lower Drug Cost Through Competition Act which my good friend from Oregon and I introduced in the last Congress and again in January and I appreciate you offering this amendment, Congressman Schrader, this morning.

This amendment is a targeted approach to fixing some of the problems on the generic side at FDA and then with the issue of high prescription drug prices. We are dealing with the issue, Mr. Chairman.

I know many of my constituents and folks around the country are deeply concerned about being able to afford the

medicine they rely on. This amendment would directly address situations like Turing Pharmaceuticals, hiking the price of an HIV drug from $13.50 to $750 over night. That is unacceptable or when Mylan raised the cost of the EpiPen by more than 400 percent. Too often, bad actors like these in the market place take advantage of monopolies, skyrocketing the price of life-saving medication simply because there is little to no competition. We are going to fix that.

The amendment creates the new competitive generic therapies program. This will provide drug sponsors better feedback before submitting an application and helps address the one major problem in FDA which is the nine percent first cycle review.

Think about that. Only nine percent of generic drug applications are approved on the first submission. If it takes three tries to get approved, 5 whole years could have gone by. That is 5 years of patients not getting a lower cost generic drug.

The amendment also creates an exclusivity incentive for drug companies to develop a generic drug where there are no generic drugs available. This will help encourage competition and drive down costs. There are no shortages of potential for increased competition, Mr. Chairman. Americans continue to feel the pressure of rising drug costs and we are addressing

that issue with this amendment.

We need to take thoughtful action to solve this issue affecting so many millions. I know everyone agrees with that. Leveraging the power of the free market and incentivizing competition among drug makers will drive down costs.

I am glad that the committee will take this amendment up and I look forward to its adoption. I yield back. Thank you.

Chairman Burgess. Will the gentleman yield?

Mr. Bilirakis. Yes, I will. Absolutely.

Chairman Burgess. I thank the gentleman for yielding. I will just say generic drugs are an American success story and have saved probably a trillion and a half dollars for American consumers over the last 10 years.

I want to thank Representatives Schrader and Bilirakis for their leadership, for working so hard to advance this legislation, and I urge my colleagues to support. I yield back to the gentleman from Florida who then yields back the balance of time. The chair thanks the gentleman. Further discussion on the amendment?

Mr. Green. Will the gentleman yield?

Chairman Burgess. The gentleman would be happy to yield.

Mr. Green. Because I don't want my own 5 minutes on this. I want to thank both Congressman Bilirakis and Congressman Schrader for working with us on the bill and I

think it is a success and just appreciate that this is how we are supposed to do legislation and I yield back. Thank you.

Chairman Burgess. The gentleman from Florida yields back. The chair thanks the gentleman. Further discussion on the amendment? For what purpose does the gentleman from California seek recognition?

Mr. Cardenas. Seek recognition to strike the last word.

Chairman Burgess. The gentleman is recognized for 5 minutes.

Mr. Cardenas. I would like to thank my colleagues Schrader and Bilirakis for working on this issue. It is incredibly important. And at the same time I would like to thank the chairman and say how much I appreciate the bipartisan work that is going on in this amendment and the bill that we are hearing today. But in addition to that, I would like to bring up something that hopefully will be taken up soon.

And I want to first thank the outreach that Representatives Peters and Costello have done to provide me and my office with informing us on the issue of the third party servicing bill which is H.R. 2118, the Medical Devices Servicing and Accountability Act, which takes modest steps to ensure that the FDA has some insight into the servicing work on sensitive medical imaging equipment, like MRIs, CTs, and

radiation therapy equipment done by third-party servicers.

As the FDA works to address third-party servicing, it is imperative that all parties servicing medical devices are at a minimum registered with the FDA. The Costello-Peters bill is a practical solution that will protect patients who not only rely on the safety of medical devices, but also on their effectiveness and their reliability.

I look forward to continuing to work with Congress members Costello and Peters and the committee as conversations continue so that this important issue can be added to the package at the full committee markup.

And once again, thank you, Mr. Chairman for the opportunity for us to take up these bills today.

Mr. Sarbanes. Will the gentleman yield?

Mr. Cardenas. Sure.

Mr. Sarbanes. I thank the gentleman for yielding. I just want to be efficient here with the use of time. I want to also thank the authors of the amendment, Messrs Schrader and Bilirakis. Obviously, this is one of a number of things that we can do to try to address drug pricing in the United States. There are many things that I think we would like to have discussed in a full hearing on the issue.

If you look at the polls out there for many Americans, the number one concern they have is the high price of

prescription drugs, drugs generally, and I think they are looking for solutions. There is concern about price gauging. I think that is a fair area of inquiry for our committee and we ought to look into that. They are concerned about overall transparency when it comes to drug pricing in the industry. There is a lot of different players out there.

It is hard sometimes to kind of follow the ball on drug pricing. We need to have some rigorous inquiry into that, so we can translate the concerns that we are hearing when we are in our districts.

Many of us have pushed for a long time to give Medicare program the authority to negotiate on drug pricing with the pharmaceutical industry. We are barred from doing that. That means in the so-called free market, a capitalist society in which we operate, the 40 million Medicare beneficiaries are not allowed to go into the marketplace and get the best price by negotiating directly with the pharmaceutical industry. That needs discussion as well.

So there are a lot of different things we can do to address the concern Americans have about high drug prices and this amendment is one of those, but it invites us to think about all the other areas that we could be exploring that could help everyday Americans with the cost of something that for many of them is life saving. It is the difference between

having a decent quality of life and feeling under a tremendous pressure and burden.

So I hope our committee will find its way on a bipartisan basis we can arrive at the kind of inquiry into this that the public deserves. And with that, I will yield back.

Mr. Cardenas. Thank you, Mr. Sarbanes. On that note with the few seconds I have with my time, I would like to thank you for bringing that up. We heard a lot about drug pricing and perhaps that is one of the top issues that every American has on their mind, not only during the 2016 election cycle, but on their minds every single day, whether they have a child that they are caring for or a senior in their family that can't afford to keep up with the pricing of drugs that we have in America.

So hopefully, Mr. Chairman, we can have a robust hearing on that issue in and of itself sooner than later and I would venture to predict that there is probably not a member on this dais on both sides of the aisle that wouldn't welcome that opportunity. So with that, hopefully, we can have that hearing soon. I yield back.

Chairman Burgess. The chair thanks the gentleman. The gentleman yields back. Further discussion on the amendment? What purpose does the gentlelady from Illinois seek recognition?

Ms. Schakowsky. I move to strike the last word.

Chairman Burgess. The gentlelady is recognized for 5 minutes.

Ms. Schakowsky. I want to take this opportunity to expand on the comments I made in my opening statement and also to follow up on some of the things that my colleagues have said.

It really is truly astonishing that the American public continues to call for action to lower drug prices and yet this committee has not held a single hearing on drug prices. We didn't hold a hearing when Mylan raised the price of EpiPen by 460 percent. That hearing happened in the House Oversight and Government Reform Committee.

We didn't hold a hearing when Martin Shkreli raised the price of a life-saving drug that had been on the market for decades by 5,000 percent. That hearing happened in the Senate Committee on Aging.

Now Chairman Alexander has agreed to hold a hearing on drug prices in the Senate Health Committee and the Republicans on this committee refuse to do the same.

In addition to the 6 in 10 Americans who believe lowering drug prices should be a top priority for Congress, 77 percent of Americans believe the price of drugs in unreasonable. And nearly 25 percent of Americans have skipped a dose of their

medications due to the cost.

This is one of the biggest healthcare crises in our country and yet, this committee, House Republicans are unwilling to even have a conversation about how to solve this crisis. And let me remind my Republican colleagues that what people are facing every day when they try to fill a prescription. Over the last 15 years, the price of insulin has increased more than 200 percent. The price of Evzio which helps to prevent a person from dying when they overdose on an opioid, increased from $690 to $4,500. From 2011 to 2016, the price of Humira increased 126 percent and now a single pen injecter of the drug, a single pen injecter of the drug is nearly $4,500.

Most concerning, price increases account for 100 percent of the pharmaceutical industry's $8.7 billion growth in earnings in 2016. Democrats have put forth several ideas on how to reform our drug pricing system and yet Republicans refuse to even hold a hearing on any of them. We should be looking for ways to make the pharmaceutical industry more transparent, especially in terms of how drug companies price their drugs when the drug comes to market, and why the price of drugs already on the market continue to rise.

We should be looking for ways for Medicare to reduce its spending on prescription drugs by allowing Medicare to

negotiate for the price of drugs or require rebates as Medicaid does.

Recently, the Office of Management and Budget Director, Mick Mulvaney, said he was looking into requiring rebates for drugs covered by Medicare. Good idea.

We should be looking into allowing patients to re-import drugs from countries like Canada, reducing exclusivity for high-cost drugs like biologics and ending anti-competitive pay-for-delay agreements. It is time for this Congress to do what the American people are asking of us and work together to find solutions to lower the price of prescription drugs.

And in addition to the cost faced by consumers, public sources of funding, Medicare, Medicaid, all of those are being driven to very high rates because of the cost of prescription drugs. That is the big driver behind healthcare costs increases.

We could do something about that. I hope we do work together to do something about that and I thank you. And unless someone wants about a minute, I yield back. Thank you. I yield back.

Mr. Green. Would the gentlelady yield?

Ms. Schakowsky. Yes, I would be happy to yield.

Mr. Green. I think you made a great point about the price of prescriptions and drugs and I hope, like you do, that

our committee will actually hold a hearing to discuss some solutions to the high cost of pharmaceuticals. And with that, thank you for yielding.

Chairman Burgess. The chair thanks the gentlelady. The gentlelady yields back. Further discussion of the amendment? If there is no further discussion, the vote will occur on the amendment.

All those in favor will signify by saying aye.

All opposed no.

The amendment is agreed to.

The question now occurs on forwarding H.R. 2430, as amended, to the full committee.

All those in favor will say aye.

All opposed no.

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

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

[Whereupon, at 11:57 a.m., the subcommittee was adjourned.]