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RPTR JOHNSON

EDTR WILTSIE

CONTINUED MARKUP OF H.R. 6, 21st CENTURY CURES ACT

THURSDAY, MAY 21, 2015

House of Representatives,
Committee on Energy and Commerce,
Washington, D.C.

The committee met, pursuant to call, at 8:40 a.m., in Room 2123, Rayburn House Office Building, Hon. Fred Upton [chairman of the committee] presiding.

Present: Representatives Upton, Barton, Whitfield, Shimkus, Pitts, Walden, Murphy, Burgess, Blackburn, Latta, McMorris Rodgers, Harper, Lance, Guthrie, Olson, McKinley, Pompeo, Kinzinger, Griffith, Bilirakis, Johnson, Long, Ellmers, Bucshon, Flores, Brooks, Mullin, Hudson, Collins, Cramer, Pallone, Rush, Eshoo, Engel, Green, DeGette, Doyle, Schakowsky, Butterfield, Matsui, Castor, Sarbanes, McNerney, Welch, Lujan, Tonko, Yarmuth, Clarke, Loeb sack, Schrader, Kennedy, and Cardenas.

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Staff Present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Will Batson, Legislative Clerk; Ray Baum, Senior Policy Advisor for Communications and Technology; David Bell, Staff Assistant; Sean Bonyun, Communications Director; Leighton Brown, Press Assistant; Karen Christian, General Counsel; Noelle Clemente, Press Secretary; Paul Edattel, Professional Staff Member, Health; Brittany Havens, Oversight Associate, O&I; Robert Horne, Professional Staff Member, Health; Kirby Howard, Legislative Clerk; Peter Kielty, Deputy General Counsel; Carly McWilliams, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Tim Pataki, Professional Staff Member; Graham Pittman, Legislative Clerk; Mark Ratner, Policy Advisor to the Chairman; Michelle Rosenberg, GAO Detailee, Health; Krista Rosenthal, Counsel to Chairman Emeritus; Chris Santini, Policy Coordinator, O&I; Charlotte Savercool, Legislative Clerk; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Josh Trent, Professional Staff Member, Health; Greg Watson, Staff Assistant; Ziky Ababiya, Minority Policy Analyst; Jen Berenholz, Minority Chief Clerk; Christine Brennan, Minority Press Secretary; Jeff Carroll, Minority Staff Director; Elizabeth Ertel, Minority Deputy Clerk; Eric Flamm, Minority FDA Detailee; Waverly Gordon, Minority Professional Staff Member; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Ashley Jones, Minority Director, Outreach and Member Services; Rachel Pryor, Minority Health

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Policy Advisor; Tim Robinson, Minority Chief Counsel; Samantha Satchell, Minority Policy Analyst; Kimberlee Trzeciak, Minority Health Policy Advisor; and Arielle Woronoff, Minority Health Counsel.

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The Chairman. The committee will come to order.

At the conclusion of opening statements on Tuesday, the chair called up H.R. 6, 21st Century Cures Act, and the bill was open for amendment at any point.

Are there any bipartisan amendments to the bill?

Are there any other amendments?

At this point, I would say that I have an amendment at the desk. The clerk will report the amendment.

The Clerk. Amendment to H.R. 6 offered by Mr. Upton of Michigan.

[The amendment of The Chairman follows:]

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

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The Chairman. Without objection, the reading of the amendment is dispensed with.

And I am recognized for 5 minutes in support of the amendment.

And I want to say Ms. Schakowsky has got an amendment to this amendment. Is that correct?

So at this point I will ask the clerk to report the title of the Schakowsky amendment.

The Clerk. Amendment to the amendment offered by Mr. Upton of H.R. 6 offered by Ms. Schakowsky of Illinois.

[The amendment of Ms. Schakowsky follows:]

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

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

And the gentlelady is recognized for 5 minutes in support of her amendment.

Ms. Schakowsky. Thank you so much, Mr. Chairman.

This is a great day. I rise today to offer an amendment that will greatly improve transparency in drug prices. While I intend to offer and withdraw this amendment, this is an important discussion that this committee should have.

My amendment is very simple. It would require any drug manufacturer seeking FDA approval for a drug to disclose the research and development costs of developing that drug. It would also require them to identify any NIH funding that was used to offset their R&D costs. Finally, it would require the Secretary of HHS to make this information publicly available.

This would allow us to understand how much each drug costs to deliver. We keep hearing that drug companies need to be incentivized to produce more drugs, but I am not convinced. The cost of production of a particular drug is hidden from view, and we are just left with estimates based on researchers getting protected information from drug companies on the average cost of drugs.

That is no longer good enough. If drug companies are going to make the argument that they need more exclusivity, we need to have the data to prove that. We continue to see drugs come to market to address critical health problems that are simply unaffordable for most people.

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We have the data on one such drug, and the evidence is clear that the drug company is taking advantage of the system.

Sovaldi, the new hepatitis C treatment that came to market this year, costs \$84,000 for a course of treatment. And the drug manufacturer will tell us that this cost reflects investments made to develop the drug, but Gilead bought the company that owns Sovaldi for \$11 billion and is on pace to recoup that investment in a single year.

In fact, if Sovaldi were used to treat each of the 3 million hepatitis C patients in the United States, it would cost around \$300 billion, or about the same amount we annually spend for all other drugs combined.

Now we have a bill where we are increasing Federal funding for NIH research in the hopes that these dollars accelerate the number and pace that new cures and treatments get to market, cures and treatments that will be developed by drug companies.

This bill also initially had five exclusivity provisions, and I am glad that most have been dropped. But I remain concerned about the remaining one, which would allow companies in one of the most profitable industries to make more revenue because there is concern that they don't have enough profits to support drug development.

With the considerable investment we are making in research and the significant amount we are spending for consumers to have access to the cures and treatments that they produce, we should have more information on the cost of production.

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I agree that we must make sure that there is enough economic benefit for drug companies to invest in drug development, but it is clear, at least from the Sovaldi example, that they have gone too far. Calls for increased exclusivity seem to be more attempts to gouge the system purely to increase their bottom line, not to spur innovation.

And, as I have mentioned before, we need to think about what higher drug costs mean for Medicaid, Medicare, and the VA spending. We need to ensure that everyone can benefit from the treatments and cures we hope to advance from this legislation.

Drug price transparency alone will not solve this problem, but it will go a long way in helping us to better understand what is truly driving these exorbitant drug prices. I hope that we will be able to have a conversation about this and, hopefully, take up this issue, Mr. Chairman.

And, with that, I withdraw my amendment. Thank you.

The Chairman. The gentlelady withdraws her amendment.

I will now recognize myself for 5 minutes in support of the amendment.

This manager's amendment reflects additional improvements to an already bipartisan bill, H.R. 6. And, again, I want to compliment Mr. Pallone and Ms. DeGette after our successful subcommittee markup just this last week.

I want to highlight some of the important changes that are included in the manager's amendment. We committed to providing

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additional funding for the FDA. The manager's amendment does just that through the creation of an annual Cures Innovation Fund.

The Cures Innovation Fund will help fund regulatory modernization activities at the FDA, including the qualification of biomarkers -- very important -- and placing patients' perspectives at the center of the drug and device approval process.

The bill also ensures privately funded user fee payments at the FDA no longer face the threat of sequester. This again has been a bipartisan idea from the get-go. It reflects the bill that Mr. Lance has introduced in the past. This issue has been raised by agency officials and leaders across America's healthcare industry as a real obstacle to advancing innovation. And I am glad that the 21st Century Cures addresses this issue once and for all. FDA user fees were never intended, I think, to be part of the sequester, and they were.

The manager's amendment also makes improvements to ensure the FDA can attract and hire the best and the highest experts. Major provision. And, as we committed to from day one, the 21st Century Cures will be fully offset. We said that.

The manager's amendment includes a number of what I consider commonsense reforms to fully pay for the costs of the bill. The committee has shown that it can come together to fund priorities that we all care about and do it in a fiscally responsible way.

I look forward to continuing to work with Republicans and Democrats not only on this committee, but within our leadership and

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the Budget Committee, to improve, reshape, and consider other offsets as the 21st Century Cures bill heads to the House floor.

Finally, the amendment includes H.R. 789, the Tick-Borne Disease Research Accountability and Transparency Act of 2015, which passed the House last year and we moved through this committee.

I would also note, in a good conversation last night with Bobby Rush, he shared with me a number of proposals that he would like to have included. And, in fact, in just the hours that it took to prepare the manager's amendment, we accepted some of those as part of this manager's amendment.

And even though it was late, I was glad to accept them. They are good. They improve the bill. And I look forward to keeping them in as part of the bill. And I appreciate his genuine and sincere interest to make sure that his concerns were addressed.

The bottom line is this: I want to say that every single member here on both sides of the aisle has something in this bill. That is good. It is going to advance and expedite the approval of drugs and devices for families across the country. It is a bipartisan effort that started, really, in December of 2013.

And I have to commend former chairman and ranking member Henry Waxman as well. He was one that also supported the bottom line of what we are doing.

But when you look at this product, as I introduced H.R. 6 -- and it had Frank's fingerprints on it, and it was still warm when Diana

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DeGette had her hand on it -- as we introduced it earlier this week, that bill has provisions that every one of us has something in it, and I appreciate that.

Because we took the time to listen to all of you, to experts across the country. And we should be very proud of this product. And the extra time that we took to move the markup from Wednesday morning to now I think has made it a stronger bill and one that certainly unites us and moves the process forward.

So I appreciate everyone's input. I look forward to getting it passed shortly this morning. And I would yield back the balance of my time.

And I recognize the gentleman from New Jersey, the ranking member, my friend Mr. Pallone.

Mr. Pallone. Thank you, Mr. Chairman.

And let me start out by thanking you. It has been a pleasure, really, working with you on this bill. And I think, in my opinion, you really epitomize what it is all about to be an outstanding Member of Congress, Republican or Democrat. You worked with us constantly and were always willing to entertain our concerns and ideas. So I know you are very proud of this bill, and you should be.

I also want to thank Congresswoman DeGette. From day one, when she trekked around the country, I guess is the best way to put it, with Chairman Upton and promoted this bill -- I mean, we are here kind of -- it is almost anticlimactic today because the amount of work that

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was put into this by so many people, but particularly the Chairman and Ms. DeGette, is unbelievable. I think the only one I went to outside of Washington was when I went to Lancaster with Mr. Pitts.

I also want to thank Chairman Pitts and our ranking member, Mr. Green, for all the work they have put into it. Not only did I get a chance to go to Lancaster, which I always wanted to, but, again, that hearing and all the hearings just showed a tremendous amount of bipartisanship and willingness to work together, which is kind of an example, in my opinion, of what this Congress and, obviously, what this committee is all about.

I also want to thank all the staff who worked so hard. I mean, this is really an incredible achievement that we have here today.

Let me just talk a little bit about the specifics in the manager's amendment before us. It reflects an effort, basically, to address several outstanding issues of importance to members, including a number of Democratic priorities that I wanted to highlight.

Following release of the 21st Century Cures draft, one message that we all heard loud and clear is the need for resources for FDA to implement the new authorities and programs included in the 21st Century Cures Act.

The manager's amendment would provide \$550 million over 5 years to enable the agency to set up or expand over a dozen new programs. These programs will help speed up and improve the process by which new medical products are developed. They will enable FDA to make better

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use of patients' knowledge and experiences in its approval decisions on new treatments.

Under these programs, FDA will help facilitate the development and use of biomarkers to improve and shorten clinical trials and they will enable FDA to create a new pathway for the development of critically needed new antibiotics for limited populations, to mention only a few. And I am glad to see this included in the amendment.

I am also pleased that the manager's amendment will address the unfortunate sequestration of FDA user fees. I have not sported a piecemeal approach to addressing the sequester in the past. However, FDA was uniquely impacted in 2013 when \$85 million in user fees were sequestered.

As members of this committee know well, the user fee agreements are carefully negotiated by industry and the FDA to support the review of drugs and medical devices. These fees, by law, cannot be used for any other purpose than to support the approval of drugs and devices.

The inability of the agency to access this funding prevents the FDA from meeting the goals laid out in these agreements and ultimately impacts timely access to safe and effective medical treatments.

While Congress addressed this issue in 2013, we did not exempt these user fees from any future sequestration. So I am pleased that the committee has done so in this manager's amendment, providing certainty to industry and FDA that those fees will continue to be available for use.

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I also want to note my support for the inclusion of proposals of importance to my colleague, Mr. Rush, which would encourage the National Institutes of Minority Health and Health Disparities to consider ways to increase the representation of underrepresented communities, including minorities, in clinical trials as well as in the biomedical workforce.

The manager's amendment also includes offsets to the underlying bill. The included offsets were carefully negotiated by both sides, and I am glad they reflect the Democratic proposal offered by Ranking Member Green that would change the timing of reinsurance payments to Medicare part D drug plans and is based on recommendations from the HHS OIG. Overall, these proposals represent a compromise that will ensure the successful implementation of H.R. 6 and provide much needed resources to NIH and FDA.

While members and staff on both sides of the aisle have been working hard on the underlying bill and the manager's amendment, I do want to note that I received a copy of a letter yesterday sent to Chairmen Upton and Pitts from 10 prominent public health organizations, including the March of Dimes, the American Academy of Pediatrics, and ACOG.

They asked that the sections in the bill that address vaccines and immunization practices be revised to ensure that they don't have the unintended effect of undermining or impairing the processes by which the CDC makes vaccination recommendations. I know that would

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be the exact opposite of our intent. So I hope that the chairman will work with us as we move forward to ensure we get these provisions right.

And, lastly, I just want to take a moment to recognize two of my staff members, Ziky Ababiya and Brendan Hennessey, both of whom have served this committee and its members ably. And I thank you for your hard work and your service and wish them well as they move on to new opportunities. They will always be part of our team.

Again, thank you, Mr. Chairman. I can't say enough about your efforts in moving forward this bill.

The Chairman. Are there other members wishing to speak on the amendment?

The gentlelady from California is recognized.

Ms. Eshoo. Thank you very much, Mr. Chairman.

This is an important day for the committee, and even more so it is an important day for people in our country. The agencies that carry out the critical research on behalf of the American people -- they are trusted agencies.

And I have always said that the "NIH" stands for the "National Institutes of Hope." And I think that today that we have really upped the ante on hope with the work that has been done on both sides of the aisle.

So I pay tribute to everyone that has been part of this effort. It is an effort that is worthy of the American people.

I would like to thank you very specifically for two pieces of

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legislation that you have included in the manager's amendment, the first one on the Tick-borne Disease Research Accountability and Transparency Act. That was passed unanimously by the Congress. This is known as Lyme disease. This was passed unanimously by the Congress in September of 2014.

And while there is always an echo chamber on, "We don't do disease-specific legislation," I was thinking late last night that not too many of us are going to pass from this world as a result of generalities. It is going to be some disease. So I think that it is so important that you recognized that. You may not have thought of it that way. But thank you for including that legislation in the manager's amendment.

The other legislation that I introduced with Mr. Lance, who has been a wonderful partner on many successful pieces of legislation that we have introduced, and that was to -- and it was really not an easy thing to do because sequestration was the door that was closed shut, locked. No one wanted to go near it.

And I said, "Wait a minute. Wait a minute. Wait a minute. These are private sector dollars that the private sector is paying in terms of fees, not public dollars. It was the public dollars that were sequestered."

And whether you were a fan of sequester or not a fan of sequester, the private sector dollars should not have to be locked up. I even tried to trace where the dollars were going, where they were sitting,

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who had them, were they earning interest. At any rate, TMI.

But thank you for including this because these private sector dollars in the form of user fees are essential to the agency and its work and the efficiency and the efficacy of the work that is done at the agency.

So thank you for recognizing both of these and including them in your manager's amendment. I appreciate it. And, beyond my appreciation, I think that the effectiveness of them, again, is something that the American people are worthy of. So thank you.

And I yield back.

The Chairman. The gentlelady yields back.

Other members wishing to speak?

The gentleman from West Virginia, Mr. McKinley.

Mr. McKinley. Mr. Chairman, I move to strike the last word.

The Chairman. The gentleman is recognized.

Mr. McKinley. Thank you, Mr. Chairman.

And I, too, applaud the committee for its work on this piece of legislation and have been an advocate of medical research and innovation for treatment for millions of Americans coping with these chronic diseases. To that end, I prepared an amendment for today to add Alzheimer's to section 1122 of the bill, along with multiple sclerosis and Parkinson's.

Mr. Chairman, Alzheimer's is the sixth leading cause of death in this country, with an estimated 5.3 million Americans suffering from

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this disease, two-thirds of whom are women. This disease is devastating to the patients and families who provide more than 17.9 billion, billion, hours of unpaid care every year.

If we can invest in data surveillance and research, perhaps we not only may find relief for the millions of Americans, but also save the taxpayers \$226 billion in costs during 2015.

Mr. Chairman, in lieu of an amendment and as an expression of hope -- just what Congressman Eshoo just talked about, an expression of hope -- I am asking you, Mr. Chairman, that you join with me in recommending that, in lieu of an amendment, recommending that the CDC designate Alzheimer's as one of those neurological disorders, in addition to Parkinson's and MS, that they will collect the surveillance data in this new provision of the bill.

The Chairman. If the gentleman would yield, I want to compliment you for your continued pursuit of finding a cure for this awful disease that will cost our Nation hundreds of billions of dollars in future years.

I have had the opportunity to sit down with the head of the Alzheimer's Foundation on a number of different occasions, and he is personally very, very supportive of what we are doing here with H.R. 6.

And as we have spent some time with the NIH and others in the administration, they know that, you know, when this bill is signed into law and as we look back on its impacts, Alzheimer's is going to be one of the things that we are going to find a cure for.

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And there is and should be an emphasis within the NIH and others for the research to find a cure. And your help has been instrumental in making sure that we accomplish that end game result, and I appreciate your diligent hard work.

I look forward to continuing to work with you on this and indeed make it a priority within the funding scheme of the NIH to find the resources to ultimately find a cure. It impacts so many families across our Nation. Thank you.

Mr. McKinley. Thank you, Mr. Chairman.

The Chairman. The gentleman yields back.

Other members wishing to speak on the amendment.

Mr. Rush. Mr. Chairman.

The Chairman. The gentleman from Illinois, Mr. Rush, is recognized.

Mr. Rush. Mr. Chairman, in the spirit of this lovefest that we are engaging in this morning, I certainly want to commend both yourself and the ranking member, Frank Pallone, and all the other members who participated so sacrificially in terms of their time and efforts to bring this particular bill to this place right now that we are in.

Mr. Chairman, this really kind of blows your mind, considering all the angst and animosities and the other kinds of engagements that we have been engaged with in terms of deliberations over this past few months. To be at this moment tells you that, despite what might be political differences, when it really gets down to it, when we wipe

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all of our ambitions and our differences aside, this committee can come together for the interests of the American people.

I think that this is a testimony that all the American people, no matter where you live, no matter their race, creed, or color, that when we are really committed, when we are really up against the wall, when we really determine what is the central interests of our constituencies, we can come together, realizing there is not a dime's worth of difference in our Nation as it relates to our people.

We might reside in different regions. We might be in different time zones. We might be of different nationalities. We might believe in different things. But when it really comes together, when we are really faced with the issues that we are concerned about, the overall health of our Nation, then this committee can rise beyond its pettiness and in a most powerful and succinct way deliver the product that the American people are really seeking.

I think this is a point of departure for this committee. I foresee the day when we can work on energy and other issues that are common to our Nation and common to the citizens of our Nation.

Mr. Chairman, I just want to again applaud you for your commitment, along with the ranking member, to make sure that all of our concerns are heard, all of our interests are heard, and that they are given proper discussion and proper input and that you lead, Mr. Chairman, from not in front, but from behind. Your membership, your members on this committee, on both sides of the aisle can look to you

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for some conscientious work on their behalf.

Mr. Chairman, I just want to again commend you and commend Ranking Member Pallone for all your efforts and Member DeGette for her interest and Gene Green for his outstanding leadership on this.

Mr. Chairman, I must say that there is a saying in our culture, "Better late than never." And I certainly am proud that, although somewhat late -- and there is a reason for the lateness of my measures.

My health expert on my committee, Mr. Orlando Jones, his grandfather passed right at a critical moment. And so he had to take some time off to be with his family. And so, at a strategic point in terms of the progress and the process here, he was absent. So that put us behind.

But, notwithstanding that, Mr. Chairman, when I brought it to you on the floor yesterday, I looked into your eyes and I told you how important this was. And I think, when I spoke to your heart from my heart, you heard the cries of those who are in my community who need this opportunity to advance and to have access to better health care.

So, again, I want to thank you and I want to thank my friend, Mr. Pallone, and each and every one of the members on this committee. We are doing a fabulous job today. You know, we are doing a great job for America today. We are doing a great job for this Congress today.

If all the Members of this U.S. Congress could just see and witness what is getting ready to happen today, I think they would be inspired and emboldened and they certainly will help see a clear direction out

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of the morass that we sometimes find ourselves in. Thank you, Mr. Chairman.

And I yield back.

The Chairman. The gentleman yields back.

And I appreciated your kind words. And I am glad you did find me on the House floor. And great staff work. And I grabbed both Frank and Diana before they left the Capitol steps to tell them that we were going to include some of those provisions, that they made sense.

Mr. Rush. Mr. Chairman, there was no way I was not going to find you.

The Chairman. I am easy to be found. I might be fast, but I am easy to be found.

The gentleman from Oregon is recognized for 5 minutes.

Mr. Walden. Thank you, Mr. Chairman.

And it is truly a remarkable day when you think about what will come from a few pages, lots of words, and transform the lives of millions. All of our families, people all over the world, will live as a result of this work, will live better lives as a result of this work.

So I commend all of those who are involved, especially with your leadership, Mr. Chairman, and certainly Ranking Member Pallone and Congressman Pitts, my neighbor here, Congresswoman DeGette, Congressman Green, the incredible staff that we have here that have put day, night -- I can't imagine what you all have been through to

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get us to this point.

And I especially appreciate the bipartisan nature of this and the fact that all of our families are affected by health issues. In a district like mine that is some 60,000-some square miles -- it would stretch from the Atlantic to Ohio -- the issues of telehealth and just simply accessing health care are extraordinary.

I could put Mr. Welch's State in one county in my district and have room left over to graze cattle. And that is a true statement. And I could pick up a couple other New England States, too, and you wouldn't miss them.

But I say that because there are some good steps forward on telehealth in here that are really important. And so I recognize that increasing the ability of telehealth service and removing barriers to access care is really, really critical in our most remote areas.

However, we must create a safe and cost-effective path to achieve this. And I know simply expanding fee-for-service codes in Medicare in order to advance telehealth as quickly as possible is going to cost a lot. So the language in the 21st Century Cures represents a real solid step forward and a very thoughtful discussion of further incorporating telehealth into our healthcare delivery system.

We have had a bipartisan telehealth working group for some time taking a look at these issues. And so I look forward to completing that journey over time by working with you and others on the committee and the telehealth working group as we continue our efforts to make

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available to rural Americans the telehealth services that they need.

But congratulations. I think, Mr. Chairman, you have put your heart and soul into this, and it shows in the words and pages before us. And it will transform and save lives for generations to come.

With that, I yield back.

The Chairman. Thank you, my friend.

Mr. Engel from New York.

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

I want to just echo what people have said, but I think it is important for many of us to say it. What has happened in the past days and certainly in the past 24 hours under your leadership and Mr. Pallone's leadership has shown why this is such a great committee, why so many people want to be on this committee.

It is bipartisan. We work together. We really make an impact on people's lives. And when all is said and done, that is why we are all here on both sides of the aisle, because we want to make positive impacts on people's lives. And when you are talking about health care, it is obviously very personal to everybody. And so I am proud of the work that we have done.

I want to thank you, Mr. Chairman, for doing that, and thank you, Mr. Pallone, for representing us so ably on this side of the aisle.

When the Democrats met yesterday and we tried to figure out what we liked, what we didn't like, what we wanted to see changed, I know Mr. Pallone went to you, Mr. Chairman, and you were very positive in

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working with us to move this bill to a point where we can really be enthused about it. So I really want to thank you for that.

I want to just highlight two issues that I feel are very important to me. That is the legislation language on biomarkers and streamlined data review. I have long been an advocate for those suffering from rare diseases. I authored the ALS Registry Act and the two most recent Muscular Dystrophy Care Act reauthorizations.

I know how much relief and encouragement new therapies can bring to rare disease patients, which is why there ought to be straightforward ways to access the safety and effectiveness of those therapies. Biomarkers are a valuable tool in making that assessment.

And I am grateful for the opportunity to work with Congresswoman McMorris Rodgers on this issue and am pleased to see it addressed in the bill text. And I am also pleased to see language included on streamlined data review, an issue I was glad to work on with Congressman Burgess.

I believe that making the drug indication approval process more efficient when a drug has already been proven to be safe just makes good common sense. It is really a positive thing that we are doing. So doing so will free up valuable FDA staff time and, more importantly, ensure that critical therapies can reach patients as expeditiously as possible.

So, again, thank you, Mr. Chairman, thank you, Mr. Pallone, thank you, Chairman Pitts, Ranking Member Green, Congresswoman DeGette, for

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your continued hard work on this initiative as well as your dedication to providing patients with innovative, safe, and effective therapies.

Thank you, Mr. Chairman.

The Chairman. Thank you. The gentleman yields back.

Other members?

The gentleman from Virginia, Mr. Griffith.

Mr. Griffith. Thank you, Mr. Chairman.

Move to strike the last word.

This is great work that the committee has done, and I appreciate it greatly. I had an amendment that I had prepared. Today may not be the right time, but I do want to speak about it for a minute.

In 1979, Virginia passed the first medical marijuana law in the United States. Thirty years ago friends of mine were smuggling marijuana into a local hospital where a young man was dying and wanted to spend every day that he could with his 2-year-old son.

The doctors put it into his medical charts that no one was to go into his room between 11:00 and 12:00. That is when the marijuana arrived. His food was to arrive at 12 noon. No one was to take it in. His friends would go out and get it. That is what they did for him over 30 years ago.

In discussing marijuana at a high school town hall, when I go to high schools in my district, 3 hours away from the experience that I had known as a young man with some of my friends, I tell that story.

And a hand goes up. And what usually happened was somebody would

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say, "Yeah. But what about for recreational use?" And I would tell them that I am not for recreational use.

But on this particular day, the hand went up in the audience. I called on the young man. Thirty years later, 3 hours away, a different medical community, and he looked me in the eye and he said, "They did that for my daddy, too."

We have to come up with the same policy related to medical marijuana. We can't just ignore the law. DEA needs to reschedule it. NIH needs to do research.

So, Mr. Chairman, I know that you have been supportive of some of these issues. Today is probably not the right day to offer that amendment. But I would like to, if I could yield to you, get your thoughts on this. But it is something that we need to do.

And I should probably also mention Jennifer Collins, a 15-year-old who came to visit my office. We don't know what the right dosage is, Mr. Chairman, but she is using cannabidiol with some THC. People are experimenting with it out there. Because she has gone, by using that, from 300 seizures a day to one seizure a day in epilepsy.

What we need to do is change the underlying policy and do the proper research. For those who don't believe that it is proper, do the proper research and come up with a proper policy for medical marijuana, not recreational use. It is a dangerous drug. But so are barbiturates and opiates, and we use those.

Mr. Chairman, I yield to you.

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The Chairman. If the gentleman would yield, I just want to say I share your thoughts. I have not had quite as personal experiences relating to folks seeking medical treatment as you have, though I have talked to a number of constituents who have asked for such. And, obviously, we all have had correspondence in our office.

Michigan is one of those States that does have medicinal marijuana. It was approved by the voters. And my votes on the House floor have reflected what my Michigan voters have asked me to do.

So I support the intent, certainly, of what you are doing. I asked you not to offer it today as we weren't quite prepared for it, I guess you could say, at the full committee markup.

I just want to say I will commit to working with you to see if we might be able to offer a similar-type amendment maybe before the Rules Committee and on the House floor.

I would note that I did talk yesterday with Andy Harris, who I believe is working on some type of amendment as it relates to the appropriation bills with this issue. But, certainly, as we look at 50 different States and different laws, I think that it would be worthwhile to have one standard and really figure out whether it works or not.

I know that from the constituents that I met with -- and I remember meeting a young mom with a very young child, 2, 3, 4 years old and, in the State of Illinois, as I recall her telling me, she was able to get the oil derived from the marijuana seed to prevent him from

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having epileptic fits and was hoping that, in Michigan, they would be able to do the same thing.

So I just commit to working with you and appreciate that you are not offering the amendment today and catch, perhaps, some members unprepared. But we have got some time to work on this and look forward to working with the gentleman in the future.

Mr. Griffith. Thank you, Mr. Chairman.

And I know you are sincere. And you have done great work on this underlying bill, along with all the others, Ms. DeGette, et cetera. And I do appreciate it.

And I yield back.

The Chairman. Other members wishing to speak on the amendment?

Mr. Green, the ranking member of the Health Subcommittee and a valiant partner in our efforts to get to today.

Mr. Green. Thank you, Mr. Chairman.

And I want to thank the chair and Congressman DeGette, my seatmate for at least a dozen years, for starting this effort in the 21st Century Cures. The hearings around the country -- Congressman Burgess and Congressman Olson and I did one in Houston. It was really amazing. And it led up to what we are seeing today.

I actually have a three-page speech I was going to read. But since Diana is such a good friend, I am going to share my time with her so we can move it along.

This 21st Century Cures is long overdue. It will pave the way

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for a new generation of health innovation. It will turn the corner on what has been happening over the last number of years at NIH with reduced funding and with \$10 billion of mandatory funding that is paid for.

But the whole bill is full of great things for health innovation, including FDA funding and to move those pharmaceuticals, we hope, from the lab table to the bedside.

I want to personally thank my healthcare person, Kristen O'Neill, who has done such a great job, like all of our staffs, literally working weekends and nights over the last year and a half.

So, with that, Mr. Chairman, I am going to ask unanimous consent to put my full statement in the record and yield the remainder of my time to my colleague, Congresswoman DeGette.

[The prepared statement of Mr. Green follows:]

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Ms. DeGette. Thank you very much, Mr. Green.

Today is really a great day for the patients of America. And I think that this manager's amendment, which was carved out in a bipartisan way and a very productive way, adds to the bill.

I would just urge some of the members who maybe weren't as involved in the day-to-day drafting of this bill to really go through it and see all of the things that this bill does for the patients of America.

As well as the \$10 billion in increased funding for the NIH for their research and the \$550 million for the FDA so they can help implement this, there are just a broad spectrum of reforms to the system in this bill.

And I am not suggesting people learn what Bayesian statistics and adaptive trial designs are, but I will tell you that way we are reforming the biomedical research system in this country and then adequately funding it is going to pay dividends for the patients of America, and that is why we are all so excited about this bill.

I want to just take a minute and say this bill was really crafted in the grand bipartisan tradition of this committee, in the tradition of some of the committee chair greats -- Joe Barton, John Dingell, Henry Waxman, so many others -- who believed that we can work together in a bipartisan way.

And I hope it will be the dawn, under your leadership, Mr. Chairman, and Frank Pallone's leadership on our side of the aisle of really trying to explore and find solutions together.

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And, to that end, I am going to take it upon myself to thank the staff. Because you don't come up with a bill like this just overnight on the back of an envelope. These staff members have been working day in and day out for over a year.

[Applause.]

Ms. DeGette. Yeah. And you can give them another round of applause after I read all their names, because that is my intention.

Lisa Cohen, my wonderful chief of staff, who is here. Rachel Stauffer. Elizabeth Farrar. And my entire staff who are here. And then the rest of the staff. And, you know, these are on my list not in party order because they all worked together as a team.

Tiffany Guarascio. Kristen O'Neill. Eric Flamm. Jeff Carroll. Clay Alspach. Gary Andres. Waverly Gordon. Arielle Woronoff. Kim Trzeciak. Rachel Pryor. Robert Horne. John Stone. Many, many others. All of the people from the FDA and the NIH who sat with us every day, giving us technical assistance.

So give all of those staff members another round of applause.

[Applause.]

Ms. DeGette. And, finally, our great legislative team, Mr. Pitts, Mr. Green, Mr. Pallone, and, finally, you, Mr. Chairman. You have really been a great partner.

I must say that we have had a lot of trips. I went to "The Mitten," right here, in Michigan, and we had a fabulous appearance on a rock-and-roll station talking about 21st Century Cures. The DJs

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wanted to talk about the chairman's niece, but we diverted that discussion. And now Frank's coming to my district later in June.

It has really been an extraordinary journey, and it is one that I hope will continue because we have so many important issues facing this committee. Thank you, Mr. Chairman, and congratulations to you.

I yield back.

The Chairman. Thank you again for your kind words.

Other members?

Yes. Mr. Whitfield from Kentucky.

Mr. Whitfield. Mr. Chairman, I also want to congratulate you and all the members and staff working on this issue.

One point that I just wanted to emphasize was the Energy and Commerce Committee has a lot of jurisdiction. And some people may agree and some people may not agree, but one of the things that I personally was pleased to see was that, normally, when we deal with healthcare issues -- and we are in an environment where everything has to be paid for -- that pay-for comes from health care.

And when we were having a debate on the SGR, I made the comment and some others made the comment, "Why don't we look at the entire jurisdiction of Energy and Commerce to try to come up with a pay-for?" Because there are some programs that haven't been looked at in quite a while. They are spending a lot of money. They may not be the most efficient.

So I notice that we are taking money from the Strategic Petroleum

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Reserve to help pay for this, which I think -- whether I support it or not, the concept I like because we should look at the entire jurisdiction of Energy and Commerce when we are looking at new programs and trying to pay for it.

So I just wanted to thank you all for looking outside the box and trying to come up with pay-fors for the program.

With that, I yield back the balance of my time.

The Chairman. Thank you.

Other members wishing to speak?

Mr. Butterfield of North Carolina.

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

Mr. Chairman, first let me associate myself with the words of Ms. DeGette and thank the staff and thank you and all of the stakeholders who worked together to get us to this point today. I am proud to be a part of this committee today, and I am just honored that we can pass this bipartisan legislation.

Mr. Chairman, I had come today planning to offer an amendment, but I am certainly not going to do that in the interest of time. But I simply want to say that the amendment would have been designated as Butterfield 1. And I hope that you would take a look at that, Mr. Chairman. I hope that you and Mr. Pallone will commit to me to working to include this small technical correction in the bill prior to its consideration.

Earlier this year I introduced H.R. 1537, the bipartisan

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Butterfield-McCaul Advancing Hope Act, which would permanently reauthorize the pediatric priority review voucher program, which has been heralded by patient advocacy groups and the biopharmaceutical industry as a tremendous success.

The pediatric PRV program, Mr. Chairman, addressed the market failures we have seen as drugs treating rare pediatric diseases have struggled to get to the market. The program created financial incentives for the rare pediatric disease drug development in the form of vouchers.

The PRV program costs taxpayers absolutely nothing. The PRV program costs nothing, while at the same time helping to speed treatments and potential cures to pediatric rare disease patients who desperately need them.

So I am grateful to the committee for recognizing the value of the pediatric PRV program and for including section 2152 in the base text. 2152 includes key provisions of the bipartisan Advancing Hope Act and will reauthorize the PRV program until the end of 2018. It will not cap the number of vouchers that can be awarded.

But I am concerned that, as drafted, applications submitted by companies must be both designated and awarded a voucher prior to December 31, 2018, which is when this bill sunsets the program.

My amendment provides a critical technical correction that allows a priority review voucher to be awarded when the product is approved by the FDA, even if the program has expired, so long as the application

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was designated as a rare pediatric disease product application prior to December 31, 2018.

This small correction, Mr. Chairman, will encourage drug developers to take the substantially higher risks and costs associated with investing in rare diseases and will lead to greater and more expeditious development of these life-saving treatments.

And so, Mr. Chairman, at this time I would simply yield back my time, but really request that I be given an opportunity to work with you and your staff and the ranking member and his staff to try to accommodate my request.

The Chairman. If the gentleman will yield, I look forward to working with you on this. I have to imagine that we will have a manager's amendment on the floor when it gets there. I look forward to working with you.

I know that we support finding cures for these rare pediatric diseases and making sure that the incentives are there to find those cures. So I appreciate your hard work on this. I really do.

Mr. Butterfield. You are very kind, Mr. Chairman. And thank you for your leadership.

I yield back.

The Chairman. Other members wishing to speak?

The gentleman from Pennsylvania, the chairman of the Health Subcommittee, Mr. Pitts.

Mr. Pitts. Mr. Chairman, this is a remarkable day. This is a

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remarkable piece of legislation. It is the culmination of over a year's work by this committee and our staff.

And I want to just commend Chairman Upton and Diana DeGette for their leadership, and the members on both sides of the aisle, Ranking Member Pallone and Green, and all of the members who have had a part in this process.

In this very room we have conducted over a dozen hearings and had dozens of roundtables with all the stakeholders listening to patients and caregivers and providers and innovators and investors and researchers and regulators, everyone involved in this process, and taken their advice.

And we are very blessed by the staff that we have. I just want to underline the hours, the days, the months, that they have worked around the clock on this. They deserve all the applause we can give them. They have been absolutely terrific.

This bill is going to mean good things for health care in America. And I have a constituent in the audience today who has come down from Pennsylvania, a little guy by the name of Max Schill, and his mom, and they have come for this markup.

And it is our hope that the families that are affected by rare and pediatric diseases in this country -- and there are some 10,000 diseases, 7,000 rare diseases, but only 500 cures. But it is our sincere hope, I know all of us, that this will provide the cures, the help that they so richly deserve.

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So I want Max and his mom just to be recognized, if you will help me recognize Max and Ms. Schill.

[Applause.]

Mr. Pitts. He and his mom have come from, I think, New Jersey.

Thank you, Mr. Chairman. I yield back.

The Chairman. The gentleman yields back.

Other members?

The gentlelady from California, Ms. Matsui.

Ms. Matsui. Thank you very much, Mr. Chairman.

Thank you very much, Mr. Chairman, the ranking member, Mr. Pallone, Chairman Pitts, Ranking Member Green, and particularly Ms. DeGette.

I really do appreciate the bipartisan strides that the committee has made on the policy on this 21st Century Cures legislation, and I especially appreciate the conversation and the debate the last couple of days to make this better. I do appreciate that very much. This 21st Century Cures legislation is a good thing. I appreciate the attention to NIH and FDA and the focus on helping patients, especially those with rare diseases.

We all know someone in our family or in our districts, but I particularly feel like I have a personal stake in this. My late husband had a rare disease. And so I am affected, as are many families, regarding a rare disease. I think rare diseases open up the window to cures for other types of diseases, and we need to stand up for

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everyone who has been affected.

The NIH funding in this legislation is a great accomplishment, and I congratulate everyone who has been involved in this. Investment in research is undoubtedly the first step in reaching cures. The second step is development, which FDA oversees.

I am pleased that we have now included funding for FDA in this bill. This bill makes changes to the way the FDA does certain things. And we need to make sure that we are not creating unfunded mandates that hinder FDA's ability to follow through on what we are asking the agency to do.

Also, I just want to say, Mr. Chairman, thank you for removing the 340B provision from this amendment. 340B is a vital program for our Nation's safety-net hospitals and clinics, such as the Ryan White clinics and hemophilia treatment centers.

I just have to say that the 340B program was designated to allow clinics and safety-net hospitals to stretch scarce resources in order to provide these vital services to the underserved.

Mr. Chairman, I appreciate your attention to this important program, but I did have concerns with making changes to the program overnight. We do need to ensure that the Health Resources and Services Administration or, as we call it, HRSA, has the authority to administer and oversee this program.

I look forward to working with you, Mr. Chairman, and my colleagues that care about 340B and the stakeholders to come up with

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good policy changes that preserve and strengthen the intent of the program.

But, all in all, Mr. Chairman, this is a good day. We appreciate everything that this committee has done. This is a great committee. I love being on this committee because we do great things.

I yield back the balance of my time.

The Chairman. The gentlelady yields back.

Other members wishing to speak on the amendment?

The gentlelady, Ms. Clarke, is recognized.

Ms. Clarke. Thank you very much, Mr. Chairman.

I would like to thank you, Chairman Upton, and Ranking Member Pallone, Representative Pitts, Representative Green, and Ms. DeGette for their extremely hard work and dedication in making this bill a reality.

I would like to thank my colleagues, Representatives Butterfield, Cardenas, Lujan, Matsui, and Kennedy, whose work with me on behalf of diversity of the workforce in this bill, as well as Mr. Rush for his amendment that would incentivize inclusiveness of underrepresented communities in clinical trials.

You know, Mr. Loeb sack and I were here just remarking to one another how we couldn't have been appointed to this committee at a better time than this. This bipartisan bill represents a real movement in the 21st century. It is a joint effort to bridge the gap between medical advances and regulatory practices, building a bridge between

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the discovery, development, and delivery of new, effective, and often lifesaving research and medications and something that both parties can agree on.

Among other things, this bill invests in advancing biomedical research by establishing a 5-year \$10-billion NIH innovation fund with mandatory dollars, which would support advances in promising areas, including precision medicine and biomarkers and having a biotech incubator in my district. This legislation holds great promise.

It also supports young emerging scientists by increasing loan repayment caps for NIH researchers from \$35,000 to \$50,000 per year. Outstanding. This bill also includes language that would require a focus on the recruitment, retention of a more diverse biomedical workforce through the development and maintenance of a strategic plan, which would include groups traditionally underrepresented in scientific research.

So this is truly an extraordinary day, Mr. Chairman. It feels great to be moving in the 21st century. Oftentimes in this body it doesn't feel that way, but certainly in this committee today we are moving in the 21st century.

And it is my hope that, by continuing to work together, we will improve the health outcomes for all Americans and indeed have a profound impact on the health of people around the world.

With that, Mr. Chairman, I yield back.

The Chairman. The gentlelady yields back.

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The gentleman from Iowa, Mr. Loeb sack.

Mr. Loeb sack. Thank you, Mr. Chair.

I don't have a prepared statement, but I just want to make a couple of comments. I am in my ninth year here in Congress, my first year on this committee. And as my good friend, Ms. Clarke, just mentioned, we were remarking about what a great time it is to be on this committee because of the achievements that we are seeing today.

I still have some issues with pay-fors on this. But, overall, this really is a tremendous honor for me to be here today with this bill because it does accomplish so much and it will in the future.

I have the University of Iowa in my district. They have a med school and the hospitals and clinics as well. Since I have been in Congress, I have heard from so many scholars who have had so many issues with the NIH funding, inadequate as it has been over the years. At the same time, I have talked to so many folks about the clinical translation part of that research as well.

And what is great about this bill is that it really addresses both aspects of that, not only the basic research, but how we then translate that research into actual cures for individuals.

And so listening to all my constituents in the past, both the professionals as well as the folks who really need these cures, whether children or adults, whatever the case may be, it is a wonderful day to be able to pass this legislation. Again, we are going to make it better as we move forward. I am confident in that.

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And I thank you, Mr. Chair. And I thank all the folks who have been working on this for really quite a long time. It is just a tremendous achievement. Thank you, Mr. Chair.

And I yield back.

The Chairman. The gentleman yields back.

Other members wishing to speak on the amendment?

The gentleman from Oregon.

Mr. Schrader. Thank you, Mr. Chairman.

I want to also congratulate you and Mr. Pallone, Ms. DeGette, Mr. Green, and Mr. Pitts on coming together here. As a new member of the committee in the minority party, it is impressive to see a committee work as well where everyone takes into account each other's concerns.

This bill, when enacted, is going to certainly spur valuable new research, innovation, and ultimately, hopefully, cures for many patients for years to come.

As a veterinarian, I particularly appreciate the fact that the discussions in sections 2101 and 2102 that provide opportunities for extra label use discussion in a very, I think, productive manner.

Earlier this week I worked with Dr. Burgess and Mr. Long to emphasize our support for those provisions that are included. The ability of pharmaceutical and medical device companies to provide this additional information beyond what is included on the labels of their products are going to help providers, payers, and patients in making their healthcare decisions to optimum advantage.

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And, finally, I want to thank you again for removing the controversial 340B language. That shows you are willing to listen and work with folks. And I think this markup demonstrates --

Mr. Shimkus. Mr. Chairman, the committee is not in order. We can't hear our colleague.

The Chairman. The gentleman will resume.

Mr. Schrader. Thank you, Mr. Chairman.

Just, finally, this markup demonstrates again, like in the SGR markup and ultimately passage on the floor, that good bipartisan leadership can drive good bipartisan members together for the betterment of this country. And I appreciate it very much.

I yield back.

The Chairman. The gentleman yields back.

Other members wishing to speak?

The gentleman from California, Mr. Cardenas.

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

The purpose of this legislation is critical to our Nation. It will help lead to discoveries and innovations in precision medicine that is not yet even imagined. One of the things that I would like to point out, I would like to thank Congresswoman Clarke for pointing out the provision relative to attracting more minorities and women into the sciences.

I would also like to point out that NIH allocated \$500 million over the next 10 years, as was mentioned by my colleague, Congresswoman

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Clarke. I appreciate these efforts by the NIH, but some of them are only targeted at finding out how to attract minorities and women and not actually engage in bringing people onboard into the field.

In addition to that, I am glad to see that the committee is taking this first step in acknowledging the need. And we must continue working to address the future of the field.

There is a beautiful movie that just came out about some students in Arizona who actually were high school students. They competed in a science contest at my alma mater at UC Santa Barbara, and they actually won. They beat MIT. They beat the college universities.

But the point I want to make is these were minority kids in a poor part of Arizona that before there was almost zero students going on to the sciences leaving that high school. But because of that effort and that reality that they could do it, too, now that high school is graduating more students that are going into the sciences than any other high school in the region.

My point is this. I want to thank the chairman and this committee for recognizing this important need that, if we are going to have innovations better and faster than ever before, we need to field every single young, smart mind to believe that they can be part of it and to be inspired to do so. And I am talking about American students. I am talking about American boys and girls.

I think it is also important to recognize that diversity in the biomedical field is not just a luxury, as I pointed out, it is a

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necessity for all of us. We are all getting older, and only God knows when and if we are ever going to need that new innovation ourselves.

I would also like to highlight that the manager's amendment would also exempt certain FDA user fee programs from sequestration, allowing the FDA to access the full amount of user fees paid by the industry.

Although it was a bipartisan agreement to restore user fees set aside in fiscal year 2013, there still is a very real possibility that sequestration could be triggered again in 2016 and again user fees could be diverted away from the FDA, delaying approvals and harming patients. As an original cosponsor of H.R. 1078, the Food and Drug Administration Safety Over Sequestration Act of 2015, I am glad to see the inclusion of this provision in the manager's amendment.

Again, I appreciate the work done by all of the members of this committee and all of our staff. This bill moves us closer to the next big innovation in precision medicine, in drug research, in biomarkers, in pediatric rare diseases, and so many other disciplines. Once again, I thank the chairman and all members for all of their wonderful work.

I yield back.

The Chairman. The gentleman yields back.

Other members wishing to speak on the amendment?

Seeing none, the vote occurs on the amendment offered by the gentleman from Michigan, Mr. Upton.

Those in favor, say aye.

Those opposed, say no.

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In the opinion of the chair, the ayes have it. The ayes have it.
The amendment is agreed to.

Are there other amendments to the bill, as amended?

The gentleman from Vermont, Mr. Welch.

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

[The amendment of Mr. Welch follows:]

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The Chairman. The clerk will report the title of the amendment.

The Clerk. Amendment to H.R. 6 offered by Mr. Welch of Vermont.

The Chairman. The amendment will be considered as read.

The staff will distribute the amendment.

And the gentleman is recognized for 5 minutes in support of his amendment.

Mr. Welch. Thank you very much.

I am going to offer this amendment and withdraw it in deference to the extraordinary work that has been done by the committee.

But, like Mr. Griffith, who, by the way, his concern about medical marijuana I share and hope our committee is going to do something on it, this amendment goes to an area that I think needs attention, and that is to allow the Federal Government, the Medicare part D program, to negotiate prices when they are purchasing prescription drugs on behalf of seniors who need that medical help.

Prescription drugs are an enormously important element of our healthcare system, and the part D program has provided immense benefits to folks who need them. But there was a law that was part of the part D program that prohibited price negotiation.

And none of us, when we are purchasing in bulk, pay retail. We get closer to a wholesale price. It would be as though you were going to buy aspirin and, if you bought 100, the unit cost would be the same as if you bought five. It doesn't make any sense.

It is not what we do in the VA program. In fact, in the VA program,

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where there is price negotiation, the price is basically 60 percent less for the same medication than it is in the part D program.

The other point Mr. Whitfield made and I think is relevant here, and that is, when we are looking at what we can do in the healthcare system, we want to find places we can save money in order to invest in other places where there is inadequate resources.

And we have managed to accomplish this in this bill, really trying to increase the opportunity for scientific research at the NIH. But health care is an irony in that a lot of folks don't have what they need, but, on the other hand, we spend an awful lot more than is necessary. One of the reasons that we do is that we don't allow for price negotiation. This would save hundreds of billions of dollars.

And, by the way, this is not unfair. I mean, it is a buyer and a seller. It is not dictating a price. It is just saying, if you are buying in bulk, you get to negotiate for a better price than if you are buying one pill at a time.

I would like to yield to my colleague, Ms. Schakowsky.

Ms. Schakowsky. Thank you, Mr. Welch.

And let me just say that I think, as we consider how to make health care more affordable, that this is very important, and we could consider this at another time because Mr. Welch is going to withdraw.

We have this great opportunity today to pass such an important bill, but we have a lot of things that we can still do. And price negotiation is one of them. We know that allowing HHS to negotiate

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for part D drug prices would save Medicare beneficiaries up to \$27 billion over 10 years. And, beyond that, it would save the government, it would save Medicare, \$156 billion over 10 years if this change were made.

So as we go forward looking for more affordable ways to provide more care at a better price to more people and to the government, I think this is such a very important decision that we could make, that price negotiation, as we do, as Mr. Welch pointed out, with the Veterans Administration, making drugs much more affordable, 60 percent less in many cases, that we ought to consider that throughout the system.

And, with that, I will yield back to Mr. Welch.

Mr. Welch. I will just finish by giving an example of how this worked. Tommy Thompson -- when he was the head of HHS during the anthrax scare, the price of Cipro was \$4.67 per dose. Tommy Thompson negotiated with the prescription drug companies and bought 100 million and paid \$0.95 per dose with an option to purchase another 100 million at \$0.85 and a third 100 million at \$0.75.

Now, the pharmaceutical company did fine, but the taxpayers also, obviously, were given a price reduction of 490 percent. So when we are looking for ways to improve the healthcare system, let's find ways where we can save the taxpayer money and the consumer money.

Mr. Chairman, as indicated, I will withdraw this amendment. And I will also end by adding to the deserved praise that you and the authors of this bill have been receiving. And I apologize that you had to

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endure so much warranted praise.

The Chairman. The gentleman's time has expired. And he withdraws his amendment.

Are there other amendments to the bill?

Mr. Rush. Mr. Chairman.

The Chairman. The gentleman from Illinois.

Mr. Rush. Mr. Chairman, I have an amendment at the desk which I intend to withdraw.

[The amendment of Mr. Rush follows:]

***** INSERT 1-4 *****

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The Chairman. The staff will distribute the amendment.

The amendment will be considered as read.

And the gentleman is recognized for 5 minutes in support of his amendment.

Mr. Rush. Thank you, Mr. Chairman.

Mr. Chairman, there are many diseases affecting minority communities that often fall by the wayside because minorities are underrepresented in clinical trials and research professionals tend to work toward solutions to diseases that they have a personal connection with and that they are personally informed of.

Mr. Chairman, cancer, heart disease, stroke, HIV/AIDS, diabetes, osteoporosis, asthma, sickle cell disease, kidney disease are just a few examples of the diseases and conditions that have been studied at length, but still disproportionately affect minority communities to a great degree.

This is why I have offered an amendment to address these disparities by requiring the National Institute on Minority Health and Health Disparities and the National Institute of Health to include within its strategic plan ways to increase representation of minority communities in clinical trials, support the development of health research workforce in underrepresented communities and support institutions that develop and produce these professionals, address disparities in maternity health outcomes by conducting research and expanding access to services that have been demonstrated to improve

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the quality and the outcomes of maternity care for vulnerable populations, and, finally, to establish a healthcare disparities education program to support, develop, and implement educational initiatives and outreach strategies that inform healthcare professionals and the public about the existence of and methods to reduce racial and ethnic disparities in health care.

These provisions, Mr. Chairman, are from my bill, H.R. 2468, the Minority Inclusion in Clinical Trials Act of 2015.

And I want to thank you again, Mr. Chairman and Ranking Member Pallone, for including two provisions, one requiring the National Institute on Minority Health Disparities to include within its strategic plan ways to increase representation of underrepresented communities in clinical trials and, two, the provision ensuring the biomedical workforce of the future includes groups from traditionally underrepresented communities, that these remain a top priority at the NIH.

And I am happy, Mr. Chairman, and, once again, ecstatic, giddy, to see these provisions included in. And I encourage my colleagues to support them.

Finally, Mr. Chairman, I, along with Ranking Member Pallone, also have a dear colleague letter that I am sending today and collecting signatures on today addressing you, Mr. Chairman, and Chairman Pitts, urging you to speak and having more hearings in the current consideration of legislation that works to address disparities in the

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delivery of health care and health outcomes for minority populations and patients.

Mr. Chairman, I will urge my colleagues on both sides of the aisle to sign onto this letter, and I urge your careful consideration of the letter's request.

And, with that, Mr. Chairman, I want to yield to the ranking member.

Mr. Pallone. Thank you. Thank you, Mr. Rush.

I just wanted to say, Mr. Chairman, again, thank you for including some of the provisions in Mr. Rush's amendment. And as we move along, we will hopefully together look at the other provisions as well.

But I do believe that, if you and Ranking Member Pitts would consider having a hearing on the issue of healthcare disparities, that would be tremendously helpful.

I know that the CBC, in particular, they have a health section where they have spent years dealing with this disparities issue and have a number of ideas that we could put forth if we had a hearing. So, hopefully, we can do that in the future.

We will send that letter to you at the end of the day.

The Chairman. If the gentleman would yield, I look forward to that letter. I think that is something that we would all welcome.

And the gentleman's time has expired.

The gentlelady from New York, Ms. Clarke.

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

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Mr. Chairman, while I recognize that Mr. Rush has withdrawn his amendment, I am in support of it. This amendment would eliminate maternal health disparities through the dissemination of effective culturally sensitive programs aimed at improving maternal health outcomes, and it would also establish a healthcare disparities education program.

African Americans are more likely to die from cancer. They are three times more likely to die from diabetes. And African American women are twice as likely to give birth to low-birth-weight infants, which can have long-term health consequences and to develop more aggressive forms of breast cancer.

There are many reasons why these health disparities exist. Lack of access to health care plays a large role in health disparities, but it is not the only reason. Generations of poverty, a lack of trust in the medical system, cultural differences, and a lack of knowledge about the importance of receiving quality health care early in one's pregnancy all impact a positive maternal health outcome.

This amendment would help us to turn the corner. It would alleviate some of the reasons that health disparities exist by expanding access to targeted strategies in both the clinical and community-based health that has demonstrated an ability to improve the quality and outcomes of maternal care for vulnerable populations.

Additionally, health disparities education programs would positively impact not only maternal health outcomes in vulnerable

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populations, but also improve the overall health and outcomes for all minority populations and, in doing so, begin to close the health disparities that exist in our Nation.

Though I am disappointed that Representative Rush's language was not fully included in the bill, I will continue to support my colleague's efforts as he works with committee staff to move this language forward. And I am grateful for the language that has been included to provide some sunshine on this issue of healthcare disparities.

With that, Mr. Chairman, I yield to the gentleman from Maryland, Mr. Sarbanes.

Mr. Sarbanes. I thank the gentlewoman for yielding.

I will be very brief. I want to also endorse the language that was put forward by Mr. Rush and withdrawn. I had the opportunity recently to attend a conference that was organized in Montgomery County, Maryland, by representatives of the African American community, the Asian American community, and Hispanic American community.

They touched on many topics, but they were unified in their call for more attention at the Federal level to the issue of health disparities and very eager for opportunities to access better data, to explore these opportunities for community-based initiatives and other efforts that can help to reduce disparities within those communities.

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So I think Mr. Rush's proposal is an excellent one. I also like the idea of hearings that could be dedicated to this topic and improving that conversation.

And, with that, I yield back to the gentlelady. Thank you.

The Chairman. The gentlelady yields back her time?

Ms. Clarke. I do, Mr. Chairman.

The Chairman. The amendment has been withdrawn.

Are there further amendments to the bill?

Seeing none, the question occurs on favorably reporting H.R. 6, as amended, to the House. And we will ask for a roll call vote.

The clerk will call the roll.

The Clerk. Mr. Barton?

Mr. Barton. Yes.

The Clerk. Mr. Barton votes aye.

Mr. Whitfield?

Mr. Whitfield. Aye.

The Clerk. Mr. Whitfield votes aye.

Mr. Shimkus?

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Pitts?

Mr. Pitts. Aye.

The Clerk. Mr. Pitts votes aye.

Mr. Walden?

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Mr. Walden. Aye.

The Clerk. Mr. Walden votes aye.

Mr. Murphy?

[No response.]

The Clerk. Mr. Burgess?

Mr. Burgess. Aye.

The Clerk. Mr. Burgess votes aye.

Mrs. Blackburn?

[No response.]

The Clerk. Mr. Scalise?

[No response.]

The Clerk. Mr. Latta?

Mr. Latta. Aye.

The Clerk. Mr. Latta votes aye.

Mrs. McMorris Rodgers?

[No response.]

The Clerk. Mr. Harper?

Mr. Harper. Aye.

The Clerk. Mr. Harper votes aye.

Mr. Lance?

Mr. Lance. Aye.

The Clerk. Mr. Lance votes aye.

Mr. Guthrie?

Mr. Guthrie. Aye.

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The Clerk. Mr. Guthrie votes aye.

Mr. Olson?

[No response.]

The Clerk. Mr. McKinley?

Mr. McKinley. Aye.

The Clerk. Mr. McKinley votes aye.

Mr. Pompeo?

Mr. Pompeo. Aye.

The Clerk. Mr. Pompeo votes aye.

Mr. Kinzinger?

Mr. Kinzinger. Aye.

The Clerk. Mr. Kinzinger votes aye.

Mr. Griffith?

Mr. Griffith. Aye.

The Clerk. Mr. Griffith votes aye.

Mr. Bilirakis?

Mr. Bilirakis. Aye.

The Clerk. Mr. Bilirakis votes aye.

Mr. Johnson?

Mr. Johnson. Aye.

The Clerk. Mr. Johnson votes aye.

Mr. Long?

Mr. Long. Aye.

The Clerk. Mr. Long votes aye.

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Mrs. Ellmers?

Mrs. Ellmers. Aye.

The Clerk. Mrs. Ellmers votes aye.

Mr. Bucshon?

Mr. Bucshon. Aye.

The Clerk. Mr. Bucshon votes aye.

Mr. Flores?

Mr. Flores. Aye.

The Clerk. Mr. Flores votes aye.

Mrs. Brooks?

Mrs. Brooks. Aye.

The Clerk. Mrs. Brooks votes aye.

Mr. Mullin?

Mr. Mullin. Aye.

The Clerk. Mr. Mullin votes aye.

Mr. Hudson?

Mr. Hudson. Aye.

The Clerk. Mr. Hudson votes aye.

Mr. Collins?

Mr. Collins. Aye.

The Clerk. Mr. Collins votes aye.

Mr. Cramer?

Mr. Cramer. Aye.

The Clerk. Mr. Cramer votes aye.

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Mr. Pallone?

Mr. Pallone. Aye.

The Clerk. Mr. Pallone votes aye.

Mr. Rush?

Mr. Rush. Aye.

The Clerk. Mr. Rush votes aye.

Ms. Eshoo?

Ms. Eshoo. Aye.

The Clerk. Ms. Eshoo votes aye.

Mr. Engel?

Mr. Engel. Aye.

The Clerk. Mr. Engel votes aye.

Mr. Green?

Mr. Green. Aye.

The Clerk. Mr. Green votes aye.

Ms. DeGette?

Ms. DeGette. Aye.

The Clerk. Ms. DeGette votes aye.

Mrs. Capps?

[No response.]

The Clerk. Mr. Doyle?

Mr. Doyle. Yes.

The Clerk. Mr. Doyle votes aye.

Ms. Schakowsky?

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Ms. Schakowsky. Aye.

The Clerk. Ms. Schakowsky votes aye.

Mr. Butterfield?

Mr. Butterfield. Aye.

The Clerk. Mr. Butterfield votes aye.

Ms. Matsui?

Ms. Matsui. Aye.

The Clerk. Ms. Matsui votes aye.

Ms. Castor?

Ms. Castor. Aye.

The Clerk. Ms. Castor votes aye.

Mr. Sarbanes?

Mr. Sarbanes. Aye.

The Clerk. Mr. Sarbanes votes aye.

Mr. McNerney?

Mr. McNerney. Aye.

The Clerk. Mr. McNerney votes aye.

Mr. Welch?

Mr. Welch. Yes.

The Clerk. Mr. Welch votes aye.

Mr. Lujan?

Mr. Lujan. Aye.

The Clerk. Mr. Lujan votes aye.

Mr. Tonko?

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Mr. Tonko. Aye.

The Clerk. Mr. Tonko votes aye.

Mr. Yarmuth?

Mr. Yarmuth. Aye.

The Clerk. Mr. Yarmuth votes aye.

Ms. Clarke?

Ms. Clarke. Aye.

The Clerk. Ms. Clarke votes aye.

Mr. Loeb sack?

Mr. Loeb sack. Aye.

The Clerk. Mr. Loeb sack votes aye.

Mr. Schrader?

Mr. Schrader. Aye.

The Clerk. Mr. Schrader votes aye.

Mr. Kennedy?

Mr. Kennedy. Aye.

The Clerk. Mr. Kennedy votes aye.

Mr. Cardenas?

Mr. Cardenas. Aye.

The Clerk. Mr. Cardenas votes aye.

Chairman Upton?

The Chairman. Votes aye.

The Clerk. Chairman Upton votes aye.

The Chairman. Other members wishing to cast a vote?

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The Clerk. Mr. Murphy?

Mr. Murphy. I would like to be the vote that puts this over the top.

The Clerk. Mr. Murphy votes aye.

The Chairman. Mrs. Blackburn?

Mrs. Blackburn. Aye.

The Clerk. Mrs. Blackburn votes aye.

The Chairman. Mr. Olson?

Mr. Olson. Aye.

And Houston Rockets beat Golden State.

The Clerk. Mr. Olson votes aye.

The Chairman. I am told that we have two members scurrying from the Capitol. We will hold just for a minute or two to see if they make it.

In the meantime, I will yield to the gentleman from Texas, Mr. Barton.

Mr. Barton. Thank you, Mr. Chairman.

May I ask how many no votes have been recorded on the roll call vote so far?

The Chairman. No. You can't yet. Not yet. I guess you can, but until the vote is closed, I don't think we are going to announce it.

Mr. Barton. Right now are there any no votes?

The Chairman. No.

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Mr. Barton. There is no no votes. Not even one?

Mr. Chairman, I may have to change my vote.

The Chairman. No, you are not. Frank says that is what he is afraid of.

Mr. Barton. But I do want to say I have been on the committee for 28 years, I think, and under Chairman Dingell and Chairman Bliley, Chairman Tauzin, myself, Chairman Dingell again, Chairman Waxman, I don't think we have ever had a major bill, a major bill, that didn't have somebody, usually me when we was in the minority, that voted no.

That is an amazing accomplishment, Mr. Chairman.

[Applause.]

Mr. Barton. And I think the committee should congratulate you and Mr. Pallone and Ms. DeGette and Mr. Pitts and all the other members who have worked in a leadership fashion. This is a real achievement.

This will change America. It will change the world for the better. And it will last. This bill will become law, and it will last for decades. That is a real achievement of your leadership and of this committee at its best, and you should be congratulated.

I yield back.

The Chairman. The gentleman yields back.

I appreciate your kind words. I just want to reiterate that this is your bill. This is America's bill. It is not mine.

Are there other members wishing to cast a vote?

Seeing none, the clerk will report the tally.

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The Chairman. Mr. Chairman, on that vote, there were 51 ayes and zero nays.

[Applause.]

The Chairman. The ayes have it, 51 to zero.

And, without objection, the staff is authorized to make technical and conforming changes to the legislation reported by the committee this morning. So ordered.

And, without objection, the committee stands adjourned.

[Whereupon, at 10:06 a.m., the committee was adjourned.]