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RPTR JOHNSON

EDTR HUMKE

MARKUP OF H.R. 6, 21<sup>ST</sup> CENTURY CURES ACT

TUESDAY, MAY 19, 2015

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

The committee met, pursuant to call, at 5:35 p.m., in Room 2123, Rayburn House Office Building, Hon. Fred Upton [chairman of the committee] presiding.

Present: Representatives Upton, Barton, Pitts, Murphy, Burgess, Blackburn, Latta, McMorris Rodgers, Bilirakis, Johnson, Ellmers, Brooks, Collins, Pallone, Green, DeGette, Schakowsky, Butterfield, Tonko, Clarke, and Cardenas.

Staff Present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Leighton Brown, Press Assistant; Karen Christian, General Counsel; Noelle Clemente, Press Secretary; Paul

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Edattel, Professional Staff Member, Health; Brittany Havens, Oversight Associate, O&I; Robert Horne, Professional Staff Member, Health; Peter Kielty, Deputy General Counsel; Alexa Marrero, Deputy Staff Director; Carly McWilliams, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Tim Pataki, Professional Staff Member; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, 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; 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; Tim Robinson, Minority Chief Counsel; Samantha Satchell, Minority Policy Analyst; and Kimberlee Trzeciak, Minority Health Policy Advisor.

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The Chairman. So, the committee will come to order. And the chair will recognize himself for an opening statement. You know, we have held dozens of roundtables and hearings on 21st century cures in this room and all across the country. We have learned about the varying challenges facing every family and community, and we have received an outpouring of ideas and support for our shared mission. And I would like to begin by thanking the countless individuals who really helped us to this moment, at the cusp of a committee vote tomorrow that will lead to a House vote, a collaboration with our colleagues in the Senate, and ultimately to deliver a bill to the President's desk and deliver 21st century cures to the patients who need them.

Thank you to the staff, too many to name, we can start on both sides of the aisle, who took the meetings, did the research, drafted the language, and sat at the negotiating table for many, many days and nights to help us develop this incredible product. Thank you to House Legislative Counsel and CBO for your tireless efforts and dedication. It is still not over. And thank you to the members of both parties who brought their best ideas, partnered with one another to make their case, and delivered so many of the policies that we welcome today.

Thank you to the experts, the advocates, and the innovators, thank you to the regulators who could have resisted our efforts to bring change, but instead chose to be our partners. Thank you to everyone here with us, individuals with personal interest and stakes in this legislation, including patients who are at the very heart of this

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effort.

Thank you to kids like Max, whose artwork shows that the policy is personal. Max is 6 years old, and he will be sitting in the front row tomorrow. Like many kids his age, he loves science, swimming, and Uno. And unlike most, he is faced with a challenge of a rare disease, Noonan syndrome. Helping Max is why we are here. Helping my friends Brooke and Brielle is why we are here. And despite our different backgrounds and interests, every single person in this room has indeed a common goal: We want more time with those that we love.

As we sit in this room and discuss the details of this bill, I can't help but think of the patients who are sitting across from their doctors, about to get the news that will change their world. One of my dear friends likened that moment to being thrown out of a plane without a parachute.

It is not just the disease that makes them feel powerless and vulnerable, the very system designed to help them has not kept pace with scientific advances. They need the next generation of treatments and cures, but they do not have until the next generation to wait. They don't care that the timelines, the failure rates, the size and costs of conducting trials are at all time highs. They just care that they can't get the therapy that is going to save them. That is why we need this bill.

A key provision of this legislation paves the way for critically ill patients to have access to better drugs and treatments, and faster.

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We have all said too many early goodbyes to people who we treasure. We have seen families robbed of a parent that will never get to see their child's milestones, like graduation, a successful career, maybe even a family.

In my district in southwest Michigan, there is a grieving and healing center for children who have lost a parent called Lory's Place. I was there on Saturday. It was modeled after Ele's Place, also in Michigan. Ele, my cousin's daughter, had only 11 months of life before being struck.

So back home is also where I met my constituent, The Champ, Muhammad Ali. Joe Frazier might have been his arch rival, but Parkinson's has been the fight of his life. He became a fierce advocate for more disease research funding. And believe me, when people saw him coming down the hall, yes, they took notice.

This morning, I talked to Lonnie, his wife, who is cheering on this effort along with her husband. It is difficult for him to speak, but he has not lost his voice. She pointed out that it is the depth and breadth of research that gives people with chronic illnesses hope to live another day. She said, "Research means so much to so many. I hope your colleagues will indeed see the light." I am happy to report to her that my colleagues have seen the light, and that is why we are here today, advancing this nonpartisan bill.

In this greatest country in the world, Americans deserve a system second to none. We can and must do better. The time for this bill,

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21st Century Cures, is now. And I would yield for an opening statement to the chairman -- or excuse me, the ranking member of the Health Subcommittee, Mr. Green from Texas, for an opening statement.

[The prepared statement of The Chairman follows:]

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Mr. Green. I want to thank the chairman for calling the markup. Last week, the markup of the 21st Century Cures package, and the swift vote out of our Health Subcommittee, marked continued progress toward boosting research and delivering hope to patients.

Over a year ago, this initiative was launched with the goal of delivering more cures and treatments to patients faster. Since then, we have been working with stakeholders across the spectrum, including patients, families, caregivers, researchers, and advocates to identify problems and inefficiencies in our regulatory system and find solutions.

And I am proud of the bill we have here today. It represents many of the ideas we received from stakeholders about how to bridge the gap between the science of cures and how we regulate these therapies. Provisions in this legislation will be better -- leverage critical Federal resources, improve the innovation ecosystem, and foster the next generation of scientists and researchers. It has received praise from both sides of the aisle, and across the medical community.

By increasing funding for NIH, this bill recognizes that medical research is essential to a robust health care system. We must continue to invest in basic and translational research to understand and diagnose and treat diseases. The bill also includes key policies to advance precision medicine, modernize the regulatory paradigm for medical products, and foster better collaboration in medical research. This includes the ADAPT Act and the SOFTWARE Act, provisions which I

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have worked with my colleagues, Congressman Shimkus and Congresswoman Blackburn respectively, for several years.

I am pleased that these provisions were in the Cures Act, and I am proud of the legislative package we are considering today. It is a bipartisan bill with the goal of patient health and safety at its core.

And I want to thank Chairman Upton, Ranking Member Pallone, Congresswoman DeGette, Chairman Pitts, and members of the committee, House Legislative Counsel, and countless stakeholders who helped us get to the point of the 21st Century Cures initiative.

But more important, I want to thank our committee and our individual staff members, who worked hours, weekdays and weekends, to help us get to this point of the bill. And again, thank you, Mr. Chairman. I yield back my time.

The Chairman. Thank you.

[The prepared statement of Mr. Green follows:]

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The Chairman. The chair would recognize the vice chair of the full committee, the gentlelady from Tennessee, Mrs. Blackburn, for an opening statement.

Mrs. Blackburn. Thank you, Mr. Chairman. And I thank you for laying out the reason that we are here, and talking about why we are here, which is constituents and those that are suffering from disease and are looking for cures and for hope, and for a way to access treatment that is most likely available, but they are having a tough time figuring that out.

I want to talk about one other component, where we have seen success when we energized innovation, and that is 100 years ago, we had the focus on summertime bringing paralysis and death many times, and frightened parents, and it was a very feared disease. FDR became permanently paralyzed, and was diagnosed with polio. He went on to help found the March of Dimes.

March of Dimes could be considered the original example of crowdfunding. Rather than asking for a doubling of an agency budget, the original fight to end polio was brought to everyday people, and they responded. March of Dimes helped to fund the development of vaccines, which eventually eradicated polio on a global basis, with the help of organizations such as the Rotary Club, of which I am a member. The success story of polio is one we should strive to understand because it began with the end in mind. The original goal of the March of Dimes was to end polio, not to study it, and certainly

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not to make incremental discoveries about it.

Once again, we need to rally the Nation and the creative minds around an unwavering commitment to find cures. We need to embrace a focused vision of improving lives, which also saves money with a cures strategy. And I am so pleased that we are beginning the markup of the 21st Century Cures legislation.

As Mr. Green mentioned, we have worked diligently to introduce H.R. 2396, the SOFTWARE Act. It is included in this package as one of the linchpin pieces. And it tailors the authority of the FDA to the realities of 21st century health IT.

Also included is the bipartisan Children's Count Act, which I introduced with Representative Capps, who is away from us recovering from knee surgery. This legislation directs the NIH to ensure that children are appropriately considered for NIH-funded studies. And finally, I introduced the Reagan-Udall Foundation reauthorization, which we put in place in 2007.

So Mr. Chairman, I thank you so much for the attention to this issue. I thank my colleagues for the bipartisan collaboration, and I yield back.

[The prepared statement of Mrs. Blackburn follows:]

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The Chairman. The chair will now recognize the gentlelady from Colorado, Ms. DeGette, for an opening statement.

Ms. DeGette. Thank you very much, Mr. Chairman. And thank you for being my partner in this journey for the last year-and-a-half. This is a wonderful bill. As many people here know, I sing in my church choir every Sunday. And this past Sunday, we had our last Sunday of the year, it was particularly bittersweet for all of us because our choir director, John Kuzma, is retiring as our leader after over 25 years.

Unfortunately and tragically, John isn't retiring by choice. John is retiring because he suffers from Parkinson's disease. And because of the progression of this terrible disease, John can no longer hold the baton with any regularity, and he can't direct our choir with the movements that he needs to. Disease has robbed this talented musician of his work and of the great passion of his life.

Sadly, too many American patients and their families share similar stories. How many lives have been cut short? How many careers have ended early and big ideas lost? How much quality time with loved ones has been missed? We are making important progress towards treating and curing diseases like Parkinson's, diabetes, cancer, and so many others. But with this committee's effort on 21st Century Cures, we are going to have the progress that will help us reach patients sooner.

This effort covers the full cycle of discovery, development, and

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delivery of new treatments and cures. Maybe most importantly, after years of resource erosion and cuts, we have a bipartisan agreement to deliver \$10 billion in important new resources for the National Institutes of Health over the next 5 years. We are helping new scientists begin their careers in research. We are helping senior researchers plan to wind down their works in ways that make sense for their lab work. We also help advance the administration's efforts on precision medicine.

The 21st Century Cures Act also modernizes clinical trials in a number of ways. We harmonize the various rules surrounding IRBs and support a centralized system. We are also supporting the use of more adaptive clinical designs and the use of Bayesian statistics. And we create a national neurological disease surveillance system to develop better data to help John Kuzma and so many others.

21st Century Cures then encourages improvements to our drug and medical device process. We incorporate the patient experience into drug development. We promote broader use of biomarkers. We support the use of real world evidence in the drug development process. And we provide for priority review of new breakthrough devices. We also support the development of new drugs and new devices.

I want to thank everybody. I want to thank Chairman Upton, I want to thank Mr. Green, Mr. Pitts, Mr. Pallone. But most of all, I want to thank our staffs. Our staffs have worked tirelessly for over a year and a half, and for most weekends the last 2 months. They have done

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an extraordinary job doing something people said we couldn't do, writing a big bill in a bipartisan way. I am looking forward to the markup tomorrow, and I am looking forward, as this bill moves along, to making it even better.

Thank you, Mr. Chairman. I yield back.

[The prepared statement of Ms. DeGette follows:]

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The Chairman. The chair would recognize the chairman emeritus of the full committee, Mr. Barton from Texas, for an opening statement.

Mr. Barton. Thank you, Mr. Chairman. I remember well 3 or 4 years ago when I came to your office and asked your permission and support to create a working group to bring experts from outside the Congress together with Members of Congress on a bipartisan basis to begin to discuss whether we could find a way to conduct medical research in a more cost efficient and more humane fashion. You were enthusiastic in endorsing the creation of that working group.

And as you well know, that group morphed into a group that you and Congresswoman DeGette established that brought in even more people, more Members, and more experts. And those working group sessions have helped to create what is now before us, H.R. 6, the 21st Century Cures Act.

I was in California not too many weeks ago, Mr. Chairman, to participate in a panel discussion with Mike Milken, NIH Director Francis Collins, and others about a topic called Accelerating Medical Research: The Bipartisan Quest for Cures. And in that panel discussion, I predicted that the bill before us would move in this Congress and would become law.

Mr. Chairman, every now and then the Congress actually does what the American people want us to do. And the work product that you are going to markup tomorrow is an example of that. This is a once every decade bill, Mr. Chairman. We don't do bills of this very often. The

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last major bill on this subject was the NIH Reform Act of 2006, 9 years ago, that came out of this committee.

I will predict, Mr. Chairman, that this bill will become law and 10, 15, 20 years from now this is the bill that this Congress will be remembered for. I am particularly proud of sections 1001, 1022, and 1023, which deal with the NIH. At your request, I just introduced those sections as stand-alone bills, and I have the bill numbers, H.R. 2419, 2420, and 2421.

Everything in this bill is a result of a bipartisan effort between yourself, the leadership of Mr. Pallone, and Ms. DeGette, and Mr. Green. And I think tomorrow you are going to see a great thing happen. You will probably report this bill with no opposition on a roll call vote. It is a tribute to your leadership, Mr. Chairman, and to the fact that the minority has dug in their heels and worked with you and others to create it.

Today is not a day to talk about what is not in the bill. It is a day to talk about what is in the bill. There are some things that I look forward to doing with you and others, we have already talked about that, the indirect costs, but that is for another day. I am very happy to support the bill, be an original cosponsor, and I look forward to working with you and others to pass it tomorrow. With that, I yield back.

The Chairman. The gentleman yields back.

[The prepared statement of Mr. Barton follows:]

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The Chairman. The chair would recognize the gentlelady from Illinois for an opening statement.

Ms. Schakowsky. Thank you, Mr. Chairman. This important bill is the result of over a year and a half of bipartisan work. And I am incredibly encouraged by the willingness on both sides to work to improve the health of millions of people suffering from diseases for which we have no treatment and no cure. There are many provisions in this legislation that are absolutely essential to achieving this goal.

Importantly, this bill includes additional discretionary and mandatory funding for NIH. Without additional funding, we simply will not be able to achieve what this bill sets out to do. Inadequate funding for biomedical research is one of the reasons so few new treatments have come to market in recent years.

Between fiscal year 2003 and 2015, NIH lost a total of more than \$8.2 billion in funding, when adjusted for inflation. And that represents a 22 percent cut in NIH funding. To put this in perspective, we are talking about nearly a full quarter of total NIH funding. And that is why I am so pleased to see that the 21st Century Cures Act helps to right this wrong. That said, there is still work to be done on this legislation, including identifying pay-fors. We simply cannot pay for this legislation by further reducing benefits for Medicare and Medicaid beneficiaries, or asking providers to accept further reductions in payments.

Time and time again, health care dollars are used to pay for

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legislation regardless of whether or not it is even related to health care. Additional cuts will further erode beneficiaries' ability to receive the care and services they need, and providers' ability to provide that care, and undermine the very essence of these treasures, Medicare and Medicaid.

In addition, I strongly believe that we need to do more to increase drug affordability, including increasing drug price transparency, and providing HHS with the ability to negotiate for drug prices. We should not be restricting access to any program that provides low-cost drugs to both providers and patients.

I look forward to working with this committee to find ways to address these issues, as it is imperative that we ensure that both individuals and payers like Medicare and Medicaid can afford the treatments we hope to advance with this legislation.

Mr. Chairman, just let me say if we are able as a Congress, or at least the majority, to eliminate the estate tax, affecting only 5,400 families in the United States, not paid for at all, then surely we can find a pay-for, if we must, for something as important as this, without eroding other health care programs like Medicare and Medicaid. Thank you, and I yield back.

Mrs. Blackburn. [Presiding.] The gentlelady yields back.

[The prepared statement of Ms. Schakowsky follows:]

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Mrs. Blackburn. Mr. Pitts is recognized, 3 minutes.

Mr. Pitts. Thank you, Madam Chairman. First, I want to thank Chairman Upton and Diana DeGette and Ranking Member Pallone and Green for their leadership in this bipartisan effort. And especially thank the staff on both sides of the aisle for their tireless work in this tremendous effort.

Today, we are considering an amendment in the nature of a substitute to the committee print for the 21st Century Cures Act, which is offered by Chairman Upton and myself, along with Representative DeGette and Ranking Members Pallone and Green. And this marks the culmination of our committee's work on this year-long endeavor.

We have had the privilege of engaging in a wide-ranging conversation with patients, caregivers, providers, innovators, investors, researchers, and regulators. In this very hearing room we have had a dozen hearings, we have had dozens of roundtables in our congressional districts around the country. The legislation that we will be sending to the House floor is the product of the valuable advice and specific ideas that we received on how Congress can help accelerate the discovery and development and delivery of promising new treatments and cures.

It incorporates the voice of the patients into the regulatory decisionmaking process, and helps address their unmet medical needs. It builds the foundation for 21st century medicine, empowering emerging scientists, and fostering collaborative research in the process. It

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streamlines clinical trials. It supports continued innovation at our Federal public health agencies. And it modernizes medical product regulation.

Not only will this bill bring hope to patients and their loved ones, but it is a resounding statement about our Nation's commitment to biomedical innovation. So I congratulate my colleagues, our staff, in preparing us for this important day. I look forward to presenting this bill to all of our colleagues in the House for their approval. With that, I yield back.

Mrs. Blackburn. The gentleman yields back.

[The prepared statement of Mr. Pitts follows:]

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Mrs. Blackburn. At this time the ranking member is recognized for 5 minutes.

Mr. Pallone. Thank you, Madam Chairwoman. The 21st Century Cures Act will have great value to patients and their families. Overall, its policies will bolster biomedical research, advance cutting-edge science, and further improve the process by which treatments are discovered and approved. Researchers, companies, patient groups, and providers alike all agree that this bill is a good step forward for our health care system.

The NIH funding included in this bill, \$10 billion over the next 5 years, is the most promising provision before us. These dollars will further basic research, which is the foundation of every drug and device brought to market, and help improve the health and lives of all Americans.

It is also important to note that this funding will serve as an effective tool to further strengthen our economy. It has been estimated that every dollar of NIH funding generates about \$2.21 in local economic growth. And in 2012, NIH-funded research supported an estimated 402,000 jobs across the United States.

While the underlying policy is complete, the issue of pay-fors is still outstanding. Offsets always prove to be difficult, and the final product must include offsets that are mutually agreeable to both Democrats and Republicans. So I hope that the GOP will continue to work with me to ensure that the 21st Century Cures Act is appropriately

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offset with the full support of the Democratic Caucus. Thank you,  
Madam Chairwoman.

Mrs. Blackburn. The gentleman yields back.

[The prepared statement of Mr. Pallone follows:]

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Mrs. Blackburn. At this time the gentleman from Ohio, Mr. Latta, is recognized for 3 minutes.

Mr. Latta. Thank you very much, Madam Chairwoman. Over the course of the last year, as the committee was tirelessly working on this legislation, I was able to host, alongside my colleague, Congressman Bill Johnson, a 21st Century Cures roundtable at Nationwide Children's Hospital in Columbus, Ohio. The roundtable provided a great opportunity for me to listen to and learn from providers, researchers, and innovators about how to better improve our Nation's healthcare system. I have also held meetings with numerous patient groups and other stakeholders on ways to better advance care for all Americans.

Additionally, as a member of the Energy and Commerce's bipartisan telehealth working group, I am particularly pleased to see language that begins to address how we can successfully adopt new technologies into our health care delivery system. The telehealth provision is designed to set the stage for the larger working group goal, which is to produce legislation that opens up a telemedicine reimbursement Medicare program in a fiscally responsible manner, while preserving patient safety and a standard of care. I look forward to continued collaboration with the working group to expand upon this provision in Cures, and to further address telehealth issues.

With that, I support the legislation in front of us today, and urge my colleagues to vote for its passage. I also want to thank, as

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has been previously mentioned by others, the great work that our staff has done on this legislation. And with that, Madam Chairwoman, I yield back.

Mrs. Blackburn. The gentleman yields back.

[The prepared statement of Mr. Latta follows:]

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Mrs. Blackburn. The gentleman from North Carolina is recognized for 3 minutes.

Mr. Butterfield. Thank you, Mrs. Blackburn. First, I would like to thank the chairman, in his absence, who has worked very hard on this legislation. Thank Mr. Pallone and our colleagues, and especially the capable committee staff and the personal office staff who have been relentless in their work to get this bill to this point.

This has indeed been an exercise in how Congress can and should conduct the business of the American people. And so I am thankful to have joined several of my colleagues, both Republican and Democrat, to spearhead the very important priorities. And the goals of many of those priorities are included in the base text of H.R. 6, which we will markup tomorrow.

I worked with Ms. Castor, for example, on advocating for legislative language similar to section 1002 on NIH funding, with Mr. McCaul of Texas on sections 2082 and 2083 on expanded access, and 2152 on the pediatric PRV program. I worked with my colleague from North Carolina, Mrs. Ellmers, on sections 2141 through 43 on vaccines, and on 3061 on disposable devices. I worked with Mr. Bilirakis of Florida on section 2151 for extension of exclusivity, and with you, Madam Chairman, on sections 2241 through 2243 on software and devices.

I am grateful to the committee for its inclusion of section 3061 regarding disposable medical technology and its recognition that disposable technologies will reduce Medicare spending and provide

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better outcomes. I want to reiterate my hope that the committee will work with me and Mrs. Ellmers to consider inclusion of a reimbursement methodology similar to the one proposed for partially disposable medical items that utilizes the existing reimburse structure for DMEs so as to avoid building an entirely different, more complex, less accurate, and less predictable reimbursement scheme.

The progress we have made on 21st Century Cures follows the most recent bipartisan effort to repeal the SGR, and provide funding for critical programs like the children's health insurance program and community health centers, among others. This is how Congress is supposed to work.

And so, Mrs. Blackburn, I look forward to working with you and with the remainder of the committee on further refinements to section 3016 on disposables, and to support the continued inclusion of the important bipartisan provisions for which I advocate. I thank you for allowing me some time. I yield back.

[The prepared statement of Mr. Butterfield follows:]

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Mrs. Blackburn. Mr. Bilirakis is recognized for 3 minutes.

Mr. Bilirakis. Thank you, Madam Chairwoman. I appreciate it very much. We have a serious problem in our great country, too many diseases and not enough treatments or cures. Over the past year, I have been honored to participate in the 21st Century Cures initiative, which examines and improves the discovery, development, delivery cycle. The 21st Century Act is giving us an opportunity to address some of the structural barriers to new cures and treatments. This is about the people who need more effective treatments but do not have access to them.

Today, we are taking a huge step forward in a bipartisan fashion. It is a great day. The passage of the 21st Century Cures Act is one of the best things Congress has done in a very long time. I am proud to have a number of provisions in this legislation.

One is the OPEN Act, the Orphan Products Extensions Now Act, introduced by my friend and myself, Representative Butterfield. Nearly one in 10 Americans suffer from a rare disease. Of the 7,000 rare diseases, 95 percent have no FDA-approved cure. That is staggering. The OPEN Act would provide a 6-month brand name exclusivity extension for companies that find a way to repurpose an existing drug to treat a rare disease.

Last August, I held a 21st Century Cures roundtable in my district. Ashley Pike, a constituent and participant, talked about how important it is to the rare disease community to incentivize the

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repurposing of drugs.

A second provision is based on a bill I introduced with my friend, Representative Lujan, the Medicare Patient Safety and Drug Abuse Prevention Act, which will establish a drug management program. This program will prevent at-risk beneficiaries from abusing controlled substances, and will monitor the prescribing and dispensing of controlled substances for our at-risk beneficiaries, helping prevent prescription drug abuse.

Another provision of mine would provide seniors with transparency in the Medicare parts A and B, by allowing seniors to better identify the out-of-pocket costs they might face for a given treatment or service, and find a side of service that is right for them and their budgets.

At another roundtable I held in Florida, I heard from representatives from medical device companies, many of which are small businesses, about the issue with FDA's Office of Combination Products. I am pleased to have a provision in this bill to require FDA to finish overdue guidance on combination products.

I urge all my colleagues to support this great bill. Let's get this done for all those who are living with or know someone with chronic or rare conditions. I yield back, Madam Chairwoman. Thank you.

Mrs. Blackburn. The gentleman yields back.

[The prepared statement of Mr. Bilirakis follows:]

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Mrs. Blackburn. Mr. Tonko, for 3 minutes.

Mr. Tonko. Thank you, Madam Chair. Part of the promise of the Cures legislation is to bring much needed innovation and modernization into our health care delivery system, and to most importantly, deliver hope to the people of our great Nation.

This bill holds much promise for those suffering from mental illness or substance abuse. For too long, substance use and mental health services have been treated as separate from the larger health care system. This has served to increase the stigma surrounding mental health and substance use disorders, and has created a scenario where many suffering from these disorders face a fragmented and oftentimes uncoordinated care delivery system.

One way we can promote integrated care is through the modernization of the requirements contained in 42 C.F.R. part 2. These regulations provide critical and needed privacy protections for those receiving treatment for substance abuse. However, these regulations were also written in an era before electronic health records, and some of the requirements of 42 C.F.R. part 2 are now creating barriers to coordinated care for individuals struggling with a substance use problem.

I have been working on a proposal to streamline these requirements with my colleague and friend from Pennsylvania, Representative Tim Murphy, whom I would like to thank not only for his work on this issue, but for his leadership on mental health and addiction issues more

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generally. We have crafted language that modernizes the 42 C.F.R. part 2 requirements for an electronic health records environment without compromising needed privacy protections that ensure a patient has the opportunity to meaningfully consent to whom has access to their substance abuse records.

I believe that these provisions fit appropriately within the interoperability title of the 21st Century Cures legislation, and I look forward to working with committee leaders on both sides to garner inclusion of this language before we move this bill to the House floor.

In closing, I would like to thank both sides of the leadership of this committee and the general membership for the outstanding work and the compromises that have been built to produce this bill, and to thank the respective staff members also. So I thank you, Madam Chair, and yield back the balance of my time.

Mrs. Blackburn. The gentleman yields back.

[The prepared statement of Mr. Tonko follows:]

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Mrs. Blackburn. Mr. Johnson is recognized for 3 minutes.

Mr. Johnson. Thank you, Madam Chair. I would also like to express my appreciation and strong support for the 21st Century Cures effort. This package is a result of a year's worth of hard work by members of this committee, their staffs, and all sorts of stakeholders, from agencies, to doctors, to patients.

I was delighted to work with my colleague, Congressman Latta, to help host a Cures roundtable in Columbus in order to hear from Ohioans about how we can best modernize cures. At the center of this effort has been the collection of stakeholder input necessary to crafting a bill that truly matters, one that is driven by American ideas and ingenuity. I am proud to serve as a member of the telehealth working group, addressing barriers in outdated policies in our Nation's health care system that work against the adoption of telehealth.

It has been and continues to be an honor to work with a such a good, bipartisan group of colleagues to advance this technology. I am pleased to work with the progress we have made thus far, and I am thankful to Chairman Upton, Ranking Member DeGette, Ranking Member Pallone, Chairman Pitts, and Ranking Member Green for their continued support throughout the Cures process. We continue working to harness the potential of telehealth to increase access, save money, improve quality, and enhance the delivery of health care in the 21st century.

I look forward to continuing these efforts and achieving the goals of the working group through sound policy. With the 21st Century Cures

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Act, America will continue to be a world leader in medical innovation.

And with that, Madam Chair, I yield back.

Mrs. Blackburn. I thank the gentleman for yielding back.

[The prepared statement of Mr. Johnson follows:]

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Mrs. Blackburn. Ms. Clarke is recognized for 3 minutes.

Ms. Clarke. Thank you, Madam Chair. And I would like to thank Chairman Upton and Ranking Member Pallone in absentia for all of their hard work and unwavering dedication to moving this bill forward. I would also like to extend a special thank you to my colleague from across the aisle, Ms. Renee Ellmers, with whom I have worked on language for this bill.

This bipartisan bill represents a joint effort to bridge the gap between medical advances and regulatory policies. Building a bridge between the discovery, development, and delivery of new, effective, and often life-saving research and medications is something that both parties agree on. Unfortunately, addressing specific diseases and medical conditions in this legislation was not feasible due to the bill's big picture approach. As a result, language supporting further research into brain aneurysms, which Representative Ellmers and I worked on, was unable to be included in the bill.

Brain aneurysms affect six million Americans, 30,000 of which will suffer a rupture each year. Of those 30,000, only 50 percent survive, and two-thirds of the survivors face permanent neurological damage. The majority of the victims are female, young girls, like Ellie Helton, who died at the tender age of 14 from a brain aneurysm. Ellie was a constituent of Representative Ellmers.

Women like Lisa Colagrossi, who was a mother, wife, and well respected television reporter in New York City. My brother had the

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privilege of working with her at WABC-TV New York. Shortly after signing off air, Lisa suffered a fatal brain aneurysm.

And women like Theresa Lawrence, who was a member of my extended family and a very proud New Yorker.

It is my hope that we would eventually be able to prevent premature deaths and brain damage by providing early detection for, and treatment of brain aneurysms. This is why I will continue to work with Representative Ellmers and the committee to find a way to move brain aneurysm research forward. And I yield back the balance of my time.

Mrs. Blackburn. I thank the gentlelady.

[The prepared statement of Ms. Clarke follows:]

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Mrs. Blackburn. Mrs. Brooks, you are recognized for 3 minutes.

Mrs. Brooks. Thank you, Madam Chairman. And I would like to thank Chairman Upton, Chairman Pitts, Ranking Member Pallone, Ranking Member Green, and Ranking Member DeGette. I would like to commend you for the significant bipartisan work that has been done on 21st Century Cures. You all are proof that meaningful bipartisan collaboration can propel solutions that will make life better for millions of Americans.

The Hoosiers I have spoken to about our path to Cures are thrilled to embrace this opportunity to accelerate the pace of medical breakthroughs. The underlying bill goes a long way towards streamlining our drug approval process. But I do believe that this legislation also needs to include much needed reforms to the often overlooked realm of biodefense.

This past fall, during the Ebola outbreak, many questioned why we didn't already have an approved vaccine, therapy, or diagnostic for the Ebola virus disease. They wanted to know why we didn't have a cure. In that spirit, I want to share with you some of the work I am doing to speed the development of biodefense medical countermeasures, or MCMs.

As members know, medical countermeasure development is unlike any other type of drug or vaccine development. It takes years, in some cases decades, to successfully test a smallpox vaccine or an anthrax treatment. And to make it even more challenging, the only purchaser of these products is the Federal Government. But without these

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products in the pipeline, our national security would be at risk and our constituents would be vulnerable.

The experience with the Ebola epidemic has raised some very important questions, how we develop new drugs and vaccines against biological threats. We know it is only a matter of when, not if, the next epidemic, pandemic, or biological event will take place. It is clear to me there are still steps Congress should consider taking to streamline the MCM development process and encourage more partners in the private sector to take on this challenging but critical task of MCM development.

I have been working with numerous stakeholders, including hospitals, first responders, and medical countermeasure developers to draft legislation that will address these issues. The ideas we are looking at include streamlining BARDA's contracting process, finding new incentives for medical countermeasures development, and better coordinating of HHS' preparedness programs. And I plan to introduce bipartisan legislation soon that will address these issues that we have not taken up in Cures.

Given the urgent need to develop new medical countermeasures to protect the American people, I hope the chairman and chairwoman will agree to work with me on this draft legislation. Thank you, Madam Chairwoman. I yield back.

Mrs. Blackburn. I thank the gentlelady for her leadership on the issue and for yielding back.

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[The prepared statement of Mrs. Brooks follows:]

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Mrs. Blackburn. Mr. Cardenas, you are recognized for 3 minutes.

Mr. Cardenas. Thank you very much, Madam Chair. I want to begin by thanking the committee, and especially Chairman Upton and Ranking Members Pallone and Green, as well as our staffs, for their tireless bipartisan work to tackle this critical issue of great importance not only to America, but to the entire world, but more importantly to the center of the universe, the 29th district of California.

This law does many things to help incentivize the research that will create the cures of tomorrow. And it is so critical, particularly to the districts like mine that have both massive health care disparities and a growing biotechnology industry. It is important that we focus on the future and ensure that it continues the growth and development of America's vibrant biomedical ecosystem.

A couple of the sections I am most pleased by are the development of precision medicine and the growing workforce base by fostering the development of young scientists. Today, the biomedical field is rapidly evolving, with new discoveries and research changing the way we think about and treat many diseases. Because of investments and innovation in this field, we have seen a drop in cancer mortality rates in California and across the country.

In the past two decades, California's cancer mortality rates declined by nearly a quarter. Female breast cancer rates declined by 36 percent. This incredible decline would not have been possible without investments by the NIH and innovations by the biomedical

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community. Yet according to the California Department of Public Health, nearly half of all Californians will develop cancer at some point in their lives. Therefore, much work remains to be done.

Precision medicine will allow us to make strides in treatment that were unimaginable only a few years ago. For instance, we can move from cancer treatment that kills cancer by devastating patients with chemo and radiation to treatment with gene therapy that targets cancer cells and leaves our friends, families, and neighbors intact. Passing this bill also provides the NIH with greater focus on where and how to invest in the development of vaccines and treatments that can further strengthen the fight against rare diseases and cancers for years to come.

I am glad to see contained in this bill language aimed at increasing investments in young scientists, specifically the increase in annual repayment cap on NIH loan repayment programs from \$35,000 to \$50,000. It is critical to recognize the role these scientists have to play in pushing the envelope of innovation and ensuring America remains the leader in biomedical research.

However, I believe the NIH innovation funding can go even further in strengthening the future medical innovation workforce by tackling the lack of women and minorities. If we truly seek to engage all stakeholders and inputs in the innovation process, this must be a diverse collection of viewpoints, including those of women and minorities.

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President Obama said it best. "We are better when we field a full team. Diversity is critical to many hopes of future growth and development." One of my colleagues mentioned that this is a once in a decade bill. Yes, it is a tremendous bill, an important bill, and that is why I thank all of my colleagues and staff for all the wonderful work. Yet at the same time, let's not wait a decade to address additional critical policy matters that our constituents need and deserve us to address.

Thank you, Madam Chairman. I yield back.

Mrs. Blackburn. The gentleman yields back.

[The prepared statement of Mr. Cardenas follows:]

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Mrs. Blackburn. Mr. Collins is recognized, 3 minutes.

Mr. Collins. Thank you, Madam Chair. I would like to join my colleagues on the committee in thanking all the people who have worked tirelessly to make this important bill come together. Chairman Upton, Subcommittee Chair Pitts, and the committee staff have spent countless hours on the 21st Century Cures bill. And I am grateful and humbled to be part of such important legislation.

I am pleased that this bill contains a few provisions that I have authored and have worked hard to include. In the spirit of enhancing and accelerating effective clinical trials, section 2061 encourages the broader application of Bayesian statistics and adaptive trial designs.

These scientific phrases may sound intricate and technical, but the policies will have an enormous impact on patients with rare diseases. When the FDA establishes guidelines for adaptive trials, as required by this provision, clinical trials used for the development of drugs will have a framework on how to tailor the trial to meet the individual DNA of the participants. Clinical trial framework will be combined with our evolving knowledge on the human genome in a way that allows pharmaceutical companies to develop and trial new drugs for specific patient populations. Bayesian statistics and adaptive trials will help unleash new groundbreaking therapies to cure and treat a variety of rare diseases.

I am also pleased to see that section 2281, the Silvio O. Conte

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Senior Biomedical Research Service provision, is included in this legislative draft. The 21st Century Cures initiative, as well as the public's overall demand for treatments and cures to deadly and debilitating diseases is putting immense pressure on the FDA. I believe that in order to obtain safe and timely approval of new therapies, we need to have some of the best and brightest minds working at the agency in charge of overseeing drug and medical device development.

The provision I have authored eliminates the cap on how many senior biomedical researchers the FDA can hire, and also allows the agency to compensate these specialists with a competitive salary. This bill is a good first step, but I do believe more can be done to incentivize top talent to join the FDA.

I look forward to working with the chairman and the committee on allowing the FDA to directly hire senior researchers without having to go through the almost year-long bureaucratic government hiring process currently in place. I am certain that these incentives will help the FDA recruit greater talent to the agency and help ensure timely, safe, and accurate approval of new drugs and therapies for patients.

Again, I want to thank the chairman for his dedication to this cause. I am proud of the work this committee has done, and am confident that this draft accomplishes the goals of the 21st Century Cures initiative as we work towards incentivizing innovation and defeating disease. And I yield back.

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Mrs. Blackburn. The gentleman yields back.

[The prepared statement of Mr. Collins follows:]

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Mrs. Blackburn. Dr. Murphy, you are recognized for 3 minutes.

Mr. Murphy. Thank you, Madam Chair. 42 C.F.R., known as part 2, governs substance abuse disorder confidentiality protections for physical and behavioral medicine records generated in substance use treatment facilities. It is well intended, but it is outdated, and part two compromises medical care, increases the risk of dangerous adverse drug interactions, and undermines health care integration.

Back in the 1970s, when part two was enacted, very few patients with substance use disorders were treated with any addiction treatment medication because there were only two approved at the time, disulfiram and methadone, and they were not commonly used. But in the last 40 years, a lot has changed. The number of medications has tripled, and there are approximately 2 million individuals currently receiving addiction treatment medications.

Notably, a publication recently by the chief medical officer at SAMHSA states, quote, "Drug interactions are a leading cause of morbidity and mortality. Methadone and buprenorphine are frequently prescribed for the treatment of opiate addictions. Patients needing treatment with these medications often have co-occurring medical and mental illnesses that require medication treatment. These clinical realities place patients being treated with methadone and buprenorphine at risk for potentially toxic drug interactions. A substantial literature has accumulated on drug interactions between either methadone or buprenorphine with other medications when

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ingested," unquote.

For example, Vivitrol and Naltrexone can both have life threatening interactions when taken at the same time as any opiate. Likewise, the three FDA-approved treatments for alcoholism all have drug interactions.

But part two perpetuates stigma by implying substance use disorders are things we should be ashamed of and hide away. They are not. They are medical conditions like heart disease or cancer, and the medical records associated with the treatment of the clinical condition of substance use disorders should be treated like all physical health records. We should not make them separate but equal.

I have been working with my colleague and friend from New York, Mr. Tonko, on this issue towards a bipartisan agreement on legislative language that would allow the sharing of substance use records on a patient with a single consent form throughout a medical system or hospital.

Under current law, the patient would have to provide written consent for every single clinician. Imagine how difficult this is for a hospital that may have hundreds or thousands of physicians in its network to let them know that this patient may be at risk with certain medications. Our language modifies the decades old part two statute for the first time since 1972 and brings it into the digital age.

Understand that recovery is not the same as being cured, and a substance use disorder will manifest itself each time a person is

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exposed to that substance.

Medical records, for example, have a notation when someone has an allergy to penicillin, for example, or any other potential side effects. It is important that a physician know when treating someone if they are at risk for an acute medical problem where they may have life threatening reactions because they are on Vivitrol, which is very beneficial to a person with addiction. But we don't want them to die because they are getting treatment.

And the second thing is it could set up this whole cycle of relapse again, which is a dangerous process. Let's reduce the relapse rates for those with substance use disorder, let's reduce the number of life threatening adverse drug reactions, and let's add bipartisan language to the underlying bill. And thank you. I yield back.

Mrs. Blackburn. The gentleman yields back.

[The prepared statement of Mr. Murphy follows:]

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Mrs. Blackburn. Mrs. Ellmers is recognized, 3 minutes.

Mrs. Ellmers. Thank you, Madam Chairman. And I too would like to take the time to thank Chairman Upton, this committee, and especially all of our staff for all the hard work that has been done on 21st Century Cures. This has been an incredible effort over the past year, and I am very excited and gratified that this is finally coming to fruition.

I would also like to thank my colleagues Mr. Butterfield and Ms. Clarke for their efforts in working together, especially Ms. Clarke, on the brain aneurysm research that we hoped to get in the bill. Although not all of our efforts will be part of the bill, I am pleased to see that important provisions focused on vaccines remains in the bill, as it is one of the most cost-effective treatments to addressing some of the most serious diseases.

I look forward to continuing working with the committee to ensure that we have a more effective system in place to provide Medicare coverage once a vaccine has been recommended by the Advisory Committee on Immunization Practices.

I am also pleased to say that this committee is committed to continue working in order to provide coverage and reimbursement for disposable medical technologies that are substitutes for DME items. This future provision will ensure the Medicare beneficiaries have access to simpler and more affordable products in the home and community setting. We also believe this policy will score as a savings to the Medicare program by allowing patients to select less expensive and

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easier to use disposable medical technologies. Moreover, increasing patient compliance can reduce hospital readmissions and help avoid other complications.

Madam Chairman, Representative Butterfield and I would like to recommend that the committee adopt a reimbursement methodology similar to what the manager's amendment proposes for partially disposable medical items. As a nurse, I understand the importance for evolving health care technology in order to improve the patient's quality of life.

I look forward to working with my colleagues on this committee in order to finalize an appropriate pathway for these technologies. I hope that all of my colleagues will join me in support of this effort to modernize Medicare's coverage and these innovative technologies.

With that, Madam Chairman, I yield back the remainder of my time.

Mrs. Blackburn. Thank the gentlelady.

[The prepared statement of Mrs. Ellmers follows:]

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Mrs. Blackburn. And I recognize Dr. Burgess for 3 minutes.

Mr. Burgess. Thank you, Madam Chair. Of course I do want to thank the chairman and ranking member, and just acknowledge that many provisions in this bill are going to be transformative in the way we study diseases, develop treatments, and deliver care. But we cannot achieve that transformation until we bring health information technology into the 21st century. Certainly doctors and researchers need to be equipped with the tools they need to improve continuity of care and unlock the promise of clinical registries and health information exchanges, the very promises that electronic health records have failed to deliver.

To keep pace with innovations in science and medicine, we will place the development of standards for interoperability squarely with the experts in the private sector. To address anticompetitive business practices, we will hold bad actors accountable, while safeguarding doctors who have invested, and sometimes invested significantly in the technology.

We have heard it said several times this afternoon that staff members, both committee staff and personal staff, have worked tirelessly. I don't know if that is entirely accurate. My staff has looked pretty fatigued at the end of a lot of days. But there have been a lot of hours logged in trying to make this happen. And we have worked across the dais to try to make certain we get the right balance.

I do have some concerns about some of the things that I have heard

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in the offset department. Some of those concerns have been mollified this afternoon. And I am grateful to the chairman for providing that information.

A hospital like Parkland Hospital is a special place for me because that is where I have learned how to practice my trade, take care of a population that is 90 percent uninsured. Certainly we want to ensure that the discoveries that are made as a result of the cures for the 21st century are available to those patients in the Parkland Hospital system.

So I hope that our changes that we are making to some of the programs will not negatively place them at a disadvantage. But congratulations to everyone who has worked on this. It is a big job, it is a big deliverable. Thank you very much, Madam Chair. I will yield back.

Mrs. Blackburn. The gentleman yields back.

[The prepared statement of Mr. Burgess follows:]

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Mrs. Blackburn. Chairman McMorris Rodgers, you are recognized for 3 minutes.

Mrs. McMorris Rodgers. Thank you, Madam Chair. I too want to join in thanking Chairman Upton for his leadership on this bipartisan initiative and his unending commitment to improving people's lives. You know, with this package, Chairman Upton's leadership is extending far beyond this committee room. It is extending into doctors' offices, hospital rooms, and homes across America.

I also want to recognize and thank my staff for their leadership and commitment on this package.

For the parents whose son was diagnosed with autism, for that double amputee waiting on a new prosthetic, or for a 58-year-old woman who just came home with breast cancer, this initiative is for them. Just recently, I hosted a 21st Century Cures roundtable in Spokane, Washington, where we heard from some of the country's preeminent leaders in biotechnology, pharmacology, and medical research. And I was reminded that the Pacific Northwest and the United States are at the forefront of medical innovation around the globe. The 21st Century Cures initiative ensures that we will remain that leader.

So thank you to the chairman and to all of my colleagues on this committee for making that happen.

I would like to begin by highlighting an advancement that really embodies the work that we are all doing here. And it is Biogen's experimental Alzheimer's treatment that was just recently announced.

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I mentioned this on the heels of a meeting that I had with Spokane's representatives from the Alzheimer's Association, some of whom face a future of a disease without a cure.

So when I see things like Biogen's cutting edge drug, which identifies and reduces the brain plaque thought to cause Alzheimer's by over 70 percent, it reminds me that there is hope for the 5 million people in this country who have been diagnosed with Alzheimer's disease. By identifying and treating the underlying causes of specific diseases, we can prevent them from happening altogether. And that is just the beginning.

The objective of our bipartisan 21st Century Cures initiative is to accelerate the development and discovery of new treatments and cures. I would like to thank Mr. Chairman for including six of my bills in the final package, bills that modernize HIPAA laws, accelerate the discovery of new cures, create research consortia to treat pediatric disorders, and bring our regulatory framework into the 21st century. It is imperative for patients to be heard when it comes to treatments that affect them. And that is why part of our initiative incorporates PROs, patient reported outcomes into the drug approval process. Whether it is ALS or breast cancer or Downs syndrome, that feedback is so important.

I have also included legislation to expedite FDA's approval process for qualifying biomarkers. In fact, of the 60 biomarkers that have been submitted to FDA for qualification, only four have been

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validated. This is a crucial part in the development of new clinical therapies. I certainly appreciate the bipartisan manner in which this was all brought forward, and I thank you all for joining me in the fight to promote medical innovation and save lives. There is no more noble cause. Thank you.

Mrs. Blackburn. The gentlelady yields back.

[The prepared statement of Mrs. McMorris Rodgers follows:]

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Mrs. Blackburn. The chair asks unanimous consent to call up and for the committee to consider H.R. 6, 21st Century Cures Act, and asks the clerk to report.

The Clerk. H.R. 6, to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

[The information follows:]

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

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

For the information of members, we are now on H.R. 6. The committee will reconvene at 10 a.m. tomorrow morning. And I remind members that the chair will give priority recognition to amendments offered on a bipartisan basis. I look forward to seeing all of you tomorrow. Without objection, the committee stands in recess.

[Whereupon, at 6:37 p.m., the committee was adjourned.]