been put on hold and no new jobs would have been created.

Mr. Speaker, this is a very good bill that should be supported by every Member of this House. It ensures that small businesses, not big corporations, have the tools they need to expand and grow, and it ensures that regular Americans on Main Street take part in the economic recovery.

The Small Business Jobs and Credit Act of 2010 spurs short-term economic recovery while paving the way for long-term business growth once the economy is back on track.

I urge a ''yes'' vote on the previous question and on the rule.

The material previously referred to by Mr. LINCOLN DIAZ-BALART of Florida is as follows:

AMENDMENT TO H. RES. 1640 OFFERED BY MR. DIAZ-BALART OF FLORIDA

At the end of the resolution add the following new section:

SEC. 4. Immediately upon the adoption of this resolution the Speaker shall, pursuant to clause 2(b) of rule XVIII, declare the House resolved into the Committee of the Whole House on the state of the Union for consideration of the bill (H.R. 5348) to amend title 5, United States Code, to reduce the number of civil service positions within the executive branch, and for other purposes. The first reading of the bill shall be dispensed with. All points of order against consideration of the bill are waived. General debate shall be confined to the bill and shall not exceed one hour equally divided and controlled by the Majority Leader and the Minority Leader or their respective designees. After general debate the bill shall be considered for amendment under the five-minute rule. During consideration of the bill for amendment, the Chairman of the Committee of the Whole may accord priority in recognition on the basis of whether the Member offering an amendment has caused it to be printed in the portion of the Congressional Record designated for that purpose in clause 8 of rule XVIII. Amendments so printed shall be considered as read. At the conclusion of consideration of the bill for amendment the Committee shall rise and report the bill to the House with such amendments as may have been adopted. The previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions. If the Committee of the Whole rises and reports that it has come to no resolution on the bill, then on the next legislative day the House shall, immediately after the third daily order of business under clause 1 of rule XIV, resolve into the Committee of the Whole for further consideration of the bill. Clause 1(c) of rule XIX shall not apply to the consideration of H.R. 5348.

(The information contained herein was provided by Democratic Minority on multiple occasions throughout the 109th Congress.)

THE VOTE ON THE PREVIOUS QUESTION: WHAT IT REALLY MEANS

This vote, the vote on whether to order the previous question on a special rule, is not merely a procedural vote. A vote against ordering the previous question is a vote against the Democratic majority agenda and a vote to allow the opposition, at least for the moment, to offer an alternative plan. It is a vote about what the House should be debating.

Mr. Clarence Cannon's Precedents of the House of Representatives, (VI, 308–311) describes the vote on the previous question on the rule as ''a motion to direct or control the consideration of the subject before the House being made by the Member in charge.'' To defeat the previous question is to give the opposition a chance to decide the subject before the House. Cannon cites the Speaker's ruling of January 13, 1920, to the effect that ''the refusal of the House to sustain the demand for the previous question passes the control of the resolution to the opposition'' in order to offer an amendment. On March 15, 1909, a member of the majority party offered a rule resolution. The House defeated the previous question and a member of the opposition rose to a parliamentary inquiry, asking who was entitled to recognition. Speaker Joseph G. Cannon (R-Illinois) said: ''The previous question having been refused, the gentleman from New York, Mr. Fitzgerald, who had asked the gentleman to yield to him for an amendment, is entitled to the first recognition.''

Because the vote today may look bad for the Democratic majority they will say ''the vote on the previous question is simply a vote on whether to proceed to an immediate vote on adopting the resolution . . . [and] has no substantive legislative or policy implications whatsoever.'' But that is not what they have always said. Listen to the definition of the previous question used in the Floor Procedures Manual published by the Rules Committee in the 109th Congress, (page 56). Here's how the Rules Committee described the rule using information from Congressional Quarterly's ''American Congressional Dictionary'': ''If the previous question is defeated, control of debate shifts to the leading opposition member (usually the minority Floor Manager) who then manages an hour of debate and may offer a germane amendment to the pending business.''

Deschler's Procedure in the U.S. House of Representatives, the subchapter titled ''Amending Special Rules'' states: ''a refusal to order the previous question on such a rule [a special rule reported from the Committee on Rules] opens the resolution to amendment and further debate.'' (Chapter 21, section 21.2) Section 21.3 continues: Upon rejection of the motion for the previous question on a resolution reported from the Committee on Rules, control shifts to the Member leading the opposition to the previous question, who may offer a proper amendment or motion and who controls the time for debate thereon.''

Clearly, the vote on the previous question on a rule does have substantive policy implications. It is one of the only available tools for those who oppose the Democratic majority's agenda and allows those with alternative views the opportunity to offer an alternative plan.

Ms. PINGREE of Maine. Mr. Speaker, I yield back the balance of my time, and I move the previous question on the resolution.

The SPEAKER pro tempore. The question is on ordering the previous question.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. LINCOLN DIAZ-BALART of Florida. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER. Pursuant to clause 8 of rule XX, further proceedings on this question will be postponed.

MESSAGE FROM THE SENATE

A message from the Senate by Ms. Curtis, one of its clerks, announced that the Senate has passed without amendments bills of the House of the following titles:

H.R. 4667. An act to increase, effective as of December 1, 2010, the rates of compensation for veterans with service-connected disabilities and the rates of dependency and indemnity compensation for the survivors of certain disabled veterans, and for other purposes.

H.R. 5682. An act to improve the operation of certain facilities and programs of the House of Representatives, and for other purposes.

The message also announced that the Senate has passed with an amendment in which the concurrence of the House is requested, a bill of the House of the following title:

H.R. 3980. An act to provide for identifying and eliminating redundant reporting requirements and developing meaningful performance metrics for homeland security preparedness grants, and for other purposes.

The message also announced that the Senate has passed bills of the following titles in which the concurrence of the House is requested:

S. 1448. An act to amend the Act of August 9, 1955, to authorize the Coquille Indian Tribe, the Confederated Tribes of Siletz Indians, the Confederated Tribes of the Coos, Lower Umpqua, and Siuslaw, the Klamath Tribes, and the Burns Paiute Tribe to obtain 99-year lease authority for trust land.

S. 2906. An act to amend the Act of August 9, 1955, to modify a provision relating to leases involving certain Indian tribes.

S. 3828. An act to make technical corrections in the Twenty-First Century Communications and Video Accessibility Act of 2010 and the amendments made by that Act.

The message also announced that pursuant to section 214 of title II, Public Law 107–252, the Chair, on behalf of the Majority Leader, appoints the following individual to serve as a member of the Election Assistance Board of Advisors:

Dr. Barbara Simons, of California.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote incurs objection under clause 6 of rule XX.

Record votes on postponed questions will be taken later.

IMPROVING ACCESS TO CLINICAL TRIALS ACT OF 2009

Mr. MCDERMOTT. Mr. Speaker, I move to suspend the rules and pass the bill (S. 1674) to provide for an exclusion under the Supplemental Security Income program and the Medicaid program for compensation provided to individuals who participate in clinical trials for rare diseases or conditions.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 1674

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Improving Access to Clinical Trials Act of 2009''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Advances in medicine depend on clinical trial research conducted at public and private research institutions across the United States.

(2) The challenges associated with enrolling participants in clinical research studies are especially difficult for studies that evaluate treatments for rare diseases and conditions (defined by the Orphan Drug Act as a disease or condition affecting fewer than 200,000 Americans), where the available number of willing and able research participants may be very small.

(3) In accordance with ethical standards established by the National Institutes of Health, sponsors of clinical research may provide payments to trial participants for out-of-pocket costs associated with trial enrollment and for the time and commitment demanded by those who participate in a study. When offering compensation, clinical trial sponsors are required to provide such payments to all participants.

(4) The offer of payment for research participation may pose a barrier to trial enrollment when such payments threaten the eligibility of clinical trial participants for Supplemental Security Income and Medicaid benefits.

(5) With a small number of potential trial participants and the possible loss of Supplemental Security Income and Medicaid benefits for many who wish to participate, clinical trial research for rare diseases and conditions becomes exceptionally difficult and may hinder research on new treatments and potential cures for these rare diseases and conditions.

SEC. 3. EXCLUSION FOR COMPENSATION FOR PARTICIPATION IN CLINICAL TRIALS FOR RARE DISEASES OR CONDITIONS.

(a) EXCLUSION FROM INCOME.—Section 1612(b) of the Social Security Act (42 U.S.C. 1382a(b)) is amended—

(1) by striking ''and'' at the end of paragraph (24);

(2) by striking the period at the end of paragraph (25) and inserting ''; and''; and

(3) by adding at the end the following:

''(26) the first $2,000 received during a calendar year by such individual (or such spouse) as compensation for participation in a clinical trial involving research and testing of treatments for a rare disease or condition (as defined in section 5(b)(2) of the Orphan Drug Act), but only if the clinical trial—

''(A) has been reviewed and approved by an institutional review board that is established—

''(i) to protect the rights and welfare of human subjects participating in scientific research; and

''(ii) in accord with the requirements under part 46 of title 45, Code of Federal Regulations; and

''(B) meets the standards for protection of human subjects as provided under part 46 of title 45, Code of Federal Regulations.''.

(b) EXCLUSION FROM RESOURCES.—Section 1613(a) of the Social Security Act (42 U.S.C. 1382b(a)) is amended—

(1) by striking ''and'' at the end of paragraph (15);

(2) by striking the period at the end of paragraph (16) and inserting ''; and''; and

(3) by inserting after paragraph (16) the following:

''(17) any amount received by such individual (or such spouse) which is excluded from income under section 1612(b)(26) (relating to compensation for participation in a clinical trial involving research and testing of treatments for a rare disease or condition).''.

(c) MEDICAID EXCLUSION.—

(1) IN GENERAL.—Section 1902(e) of the Social Security Act (42 U.S.C. 1396a(e)), is amended by adding at the end the following:

''(14) EXCLUSION OF COMPENSATION FOR PARTICIPATION IN A CLINICAL TRIAL FOR TESTING OF TREATMENTS FOR A RARE DISEASE OR CONDITION.—The first $2,000 received by an individual (who has attained 19 years of age) as compensation for participation in a clinical trial meeting the requirements of section 1612(b)(26) shall be disregarded for purposes of determining the income eligibility of such individual for medical assistance under the State plan or any waiver of such plan.''.

(2) CONFORMING AMENDMENT.—Section 1902(a)(17) of such Act (42 U.S.C. 1396a(a)(17)) is amended by inserting ''(e)(14),'' before ''(l)(3)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is the earlier of—

(1) the effective date of final regulations promulgated by the Commissioner of Social Security to carry out this section and such amendments; or

(2) 180 days after the date of enactment of this Act.

(e) SUNSET PROVISION.—This Act and the amendments made by this Act are repealed on the date that is 5 years after the date of the enactment of this Act.

SEC. 4. STUDY AND REPORT.

(a) STUDY.—Not later than 36 months after the effective date of this Act, the Comptroller General of the United States shall conduct a study to evaluate the impact of this Act on enrollment of individuals who receive Supplemental Security Income benefits under title XVI of the Social Security Act (referred to in this section as ''SSI beneficiaries'') in clinical trials for rare diseases or conditions. Such study shall include an analysis of the following:

(1) The percentage of enrollees in clinical trials for rare diseases or conditions who were SSI beneficiaries during the 3-year period prior to the effective date of this Act as compared to such percentage during the 3-year period after the effective date of this Act.

(2) The range and average amount of compensation provided to SSI beneficiaries who participated in clinical trials for rare diseases or conditions.

(3) The overall ability of SSI beneficiaries to participate in clinical trials.

(4) Any additional related matters that the Comptroller General determines appropriate.

(b) REPORT.—Not later than 12 months after completion of the study conducted under subsection (a), the Comptroller General shall submit to Congress a report containing the results of such study, together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Washington (Mr. MCDERMOTT) and the gentleman from Louisiana (Mr. BOUSTANY) each will control 20 minutes.

The Chair recognizes the gentleman from Washington.

GENERAL LEAVE

Mr. MCDERMOTT. I ask unanimous consent that all Members have 5 legislative days in which to revise and extend their remarks and include extraneous material on S. 1674.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Washington?

There was no objection.

Mr. MCDERMOTT. Mr. Speaker, many individuals who suffer from rare diseases or conditions currently face obstacles to participating in clinical research trials that may extend or improve their quality of life.

The Improving Access to Clinical Trials Act, which passed the Senate on August 5, 2010, by unanimous consent, would eliminate these barriers. This legislation would prohibit disabled beneficiaries who receive assistance from the Supplemental Security Income, or SSI program, from participating in clinical trials.

It is standard practice to reimburse clinical trial participants, not only for direct expenses associated with participation in such trials but also to reimburse them for time committed for their participation.

Moreover, it is the policy of research institutions to treat all clinical trial enrollees in a consistent manner. As a result, if compensation for expenses and time is paid to one trial enrollee, it must be paid to all. The current program rules under the SSI program regarding compensation or reimbursement from clinical trials has inadvertently created an obstacle for enrollment in such trials that can lead to life-saving therapies.

For example, approximately half of all adults with cystic fibrosis are SSI recipients. If one of these recipients were to participate in a clinical trial and received reimbursement for their commitment, that compensation would lead the Social Security Administration to redetermine whether the individual continues to meet the income and asset tests used to determine eligibility for the SSI program.

□ 1120

Thus even a modest reimbursement for clinical trial participation may prevent the majority of individuals from enrolling in trials because, under the SSI income and asset limits, it could potentially trigger a loss of their SSI benefit. As a result of this risk, very few SSI recipients who suffer from cystic fibrosis participate in clinical trials.

Given the large number of recipients with cystic fibrosis, this may have the undesired effect of slowing the pace of cystic fibrosis clinical research for all Americans, including the approval process for promising therapies that are already in the pipeline or waiting to be tested. The development of new treatments for rare diseases would benefit not only those who suffer from such conditions but the Nation as well.

SSI rules should not force recipients to choose between their current income support and health coverage and their long-term ability to manage and potentially overcome the disease that has disabled them.

In May of 2008, a number of my Democratic and Republican colleagues from the Ways and Means Committee joined me in sending a letter to the Commissioner of the Social Security Administration. We urged him to consider practical steps to allow SSI recipients to maintain their eligibility for the SSI and Medicaid benefits while participating in potentially lifesaving clinical trials. The Commissioner informed us that such a solution would require a legislative change in the law.

The legislation before us today is very similar to the bipartisan legislation that was introduced in the House by Representatives ED MARKEY and CLIFF STEARNS in June of 2009. The bill excludes the first $2,000 received as compensation or reimbursement in a clinical trial from the income and asset eligibility limits in the SSI program. It also would exclude the first $2,000 in compensation from the income tests in Medicaid.

Additionally, the legislation would require the Government Accountability Office to conduct an evaluation of the impact of this bill on enrollment of SSI recipients who participate in clinical trials. The CBO has determined that this provision, which is scheduled to sunset in 5 years following enactment, has little to no cost. Eliminating the obstacles faced by SSI recipients who suffer from a rare condition could lead to potentially lifesaving treatments or therapies that can improve the quality of life for those who suffer from these diseases.

Permitting the SSI recipients to participate in clinical research trials is the right thing to do.

I reserve the balance of my time.

Mr. BOUSTANY. Mr. Speaker, I yield myself such time as I may consume.

I rise in support of the Improving Access to Clinical Trials Act before us today.

Mr. Speaker, I was an original cosponsor of the House version of this bill introduced in June 2009. To date, there are 141 Members from both sides of the aisle who have cosponsored that House bill. The Senate version passed unanimously last month, and I urge all Members to support this needed legislation.

This bill would allow Americans with serious diseases to retain the benefits they need while they help find treatments and cures for themselves and others with similar afflictions.

In the field of medicine, clinical trials are an important tool to find new and more effective treatments for incapacitating and often deadly diseases. Under current NIH standards, sponsors of clinical research may provide modest payments to trial participants for their out-of-pocket costs and time spent participating in the trial. Such payments average about $500 per participant. That compensation must be provided to all participants if it is offered to any to ensure financial concerns don't affect the outcome of such trials. That means individuals cannot opt to not be paid for their participation in clinical trials.

Yet, under current law, such payments also must be counted as income in determining an individual's eligibility for SSI disability payments and Medicaid coverage, if they receive those benefits. That means that participating in a clinical trial could reduce or even eliminate those important benefits for some individuals. That forces individuals to choose between maintaining their current health and disability benefits and the chance to participate in a clinical trial that could improve or even cure their condition, as well as help others like them in the future. And when a large share of people with rare diseases like cystic fibrosis are receiving SSI benefits, this policy may actually prevent trials from going forward altogether, since it restricts the already small number of people able to participate in the trial in the first place.

So this bill makes a simple correction. Over the next 5 years, it directs the SSI and Medicaid programs to ignore modest compensation that program beneficiaries might receive for participation in clinical trials when determining program eligibility. This is consistent with current SSI program exemptions, as well as common sense. Importantly, given the small number of people affected and the program red tape this would actually prevent, the Congressional Budget Office estimates that this bill will result in no net costs to the Federal Government. And the legislation directs the Government Accountability Office to study this issue to ensure the bill is having its intended effects of assisting people with diseases and improving participation in clinical trials while holding the Federal program costs down.

Mr. Speaker, this is a reasonable approach that merits our support.

I reserve the balance of my time.

Mr. MCDERMOTT. Mr. Speaker, I yield 5 minutes to the gentleman from Massachusetts (Mr. MARKEY).

Mr. MARKEY of Massachusetts. I thank the gentleman from Washington State so much, and I thank my friend from Florida (Mr. STEARNS), my cosponsor of this legislation and my co-chair of the Congressional Cystic Fibrosis Caucus, for his incredible work in helping to bring this moment into being.

The Improving Access to Clinical Trials Act will enable more individuals with rare diseases to participate in clinical trials offering hope for cures to devastating diseases like cystic fibrosis. This bill is urgently needed.

Current eligibility requirements for Medicaid and Supplemental Security Income shut out many disabled and low-income Americans from participation in potentially lifesaving clinical trials. That is because, in accordance with current ethical standards, many clinical trials offer modest compensation for patient participation, which can average around $500. Low-income patients with rare diseases face a serious barrier to taking part in drug trials, as the modest fee they receive for participation counts towards their eligibility for Supplemental Security Income and Medicaid and can push their income above the established caps. This forces patients to choose between receiving the essential benefits they need to live and the opportunity to participate in a clinical trial that could improve their condition and offer hope for a cure. This is a cruel choice that no one should have to make.

The bill we are considering today addresses this situation by allowing Medicaid recipients and individuals who receive Supplemental Security Income to participate in clinical trials to provide compensation without the risk of losing their benefits, and by excluding up to $2,000 in compensation a patient receives from a clinical drug trial from his or her income calculation for Supplemental Security Income and Medicaid eligibility.

Our bill applies to rare disorders, which are defined as diseases affecting less than 200,000 people in the United States. There are more than 6,000 rare disorders that, taken together, affect approximately 25 million Americans. Examples of rare diseases include ALS, Crohn's disease, cystic fibrosis, Huntington's disease and Parkinson's disease.

The House version of this bill, which Mr. STEARNS and I introduced more than a year ago, has 141 bipartisan cosponsors. The Senate version we are considering today, which included Medicaid eligibility in addition to SSI, passed the Senate by unanimous consent on August 5. The Congressional Budget Office has determined that the bill has no cost to the Federal Government. While there is no cost to the government, for millions of Americans the benefits could be enormous—the chance to receive treatment that could dramatically improve their health.

For scientific research, clinical drug trials are an essential part of the process for searching for treatments for diseases. When testing treatments for rare diseases in particular, researchers need patient participation from a significant percentage of patients with each disease in order to produce valid results. Consequently, researchers often struggle to recruit enough patients.

□ 1130

Today, we are working to eliminate one of those barriers to participation by opening clinical trials for rare diseases to those on Medicaid and Supplemental Security Income.

This could produce dramatic advancements towards a cure for rare disorders, including cystic fibrosis. There are approximately 30,000 people living in the United States with cystic fibrosis today. In the 1950s, children with CF usually didn't live past the age of kindergarten. Now, CF patients live productive lives with a median age of 37, thanks to advances in medical research just over the last 40 years.

More than 30 potential therapies are in the CF drug development pipeline today, more than in the entire history of CF research, and many are being tested in clinical trials.

In the next 2 to 3 years, we will need more than 7,000 CF patients to participate in clinical drug trials. Three thousand CF patients participated in drug trials last year. Nearly 50 percent of the CF population receives public benefits, including SSI and Medicaid.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. MCDERMOTT. Mr. Speaker, I yield the gentleman an additional 2 minutes.

Mr. MARKEY of Massachusetts. Listen to that again: Nearly 50 percent of the CF population receives public benefits, including SSI and Medicaid.

While the average clinical trial compensation amount for a cystic fibrosis drug is $700, an individual with cystic fibrosis often has medical expenses totaling nearly $80,000 per year. Clinical research is critical to our progress towards curing rare diseases such as cystic fibrosis, especially at a time of tremendous opportunity and hope in medical research.

The bipartisan Improving Access to Clinical Trials Act will encourage patients suffering from rare diseases to participate in promising clinical research that may lead to cures, better treatment, and ultimately, saved lives, without having to worry that they could lose SSI benefits.

Our bill has been endorsed by more than 120 organizations, including the Cystic Fibrosis Foundation, the Biotechnology Industry Organization, the National Health Council, and Research!America.

Research is medicine's field of dreams from which we harvest the findings that give hope to millions of Americans that the disease that runs through their family's history may finally be cured. That is what this bill is all about, ensuring clinical trials are conducted that give families hope.

Again, I want to thank the gentleman from Florida and the leaders of the Ways and Means Committee for all of the work that you have done in making this a possibility. I urge an ''aye'' vote.

Mr. BOUSTANY. Mr. Speaker, I am pleased to yield such time as he may consume to the gentleman from Florida (Mr. STEARNS), one of the coauthors of the House bill.

(Mr. STEARNS asked and was given permission to revise and extend his remarks.)

Mr. STEARNS. Mr. Speaker, I thank my colleague from Louisiana for yielding me this time.

Obviously as a cosponsor in working with Mr. MARKEY, this is a very important bill. Mr. Speaker, this is bipartisanship in its essence. We have seen a lot of complaints both in the press and from the public about Members of Congress not getting together. Here you have a gentleman from Massachusetts and a gentleman from Florida working to cosponsor and to pass this bill. It has overwhelming support by Members here in the House. I look forward to its passage, and I commend the gentleman from Massachusetts (Mr. MARKEY) for what he is doing. We are cochairs and cofounders. We cofounded the Cystic Fibrosis Caucus some time ago. We are working, doing the Lord's work here.

Mr. Speaker, a lot of what has been said is also in my speech, and I don't necessarily want to reiterate it again. Simply put, this bill improves access to clinical trials. It will allow people with rare diseases like cystic fibrosis to participate in clinical trials that provide nominal compensation without, and this is the key part, without the risk of losing their health coverage. Senator WYDEN sponsored the bill S. 1674, and Mr. MARKEY and I sponsored H.R. 2866.

I think all of us realize clinical trials are an essential part of the process as researchers develop new treatments for diseases. When testing treatments for rare diseases in particular, researchers need a significant percent of the patient population for each disease to participate in the various trials. Because of this, they often struggle to recruit patients. They just can't find enough.

For example, let's go to the University of Alabama at Birmingham. It houses one of the Cystic Fibrosis Foundation's largest CF care centers with over 450 patients. The University of Alabama at Birmingham conducts numerous clinical trials on promising new treatments for CF patients. But when they began looking for CF patients to participate in trials for a new drug that some believe would be a game changer in the treatment of CF, they were only able to find four patients who met the trial protocol criteria. With these small numbers, the integrity of the study can be compromised if patients are not enrolled promptly. Enrollment becomes further compromised when patients choose to not participate because their Medicaid and SSI eligibility becomes at stake.

We have come a long way in treating CF. In the 1950s, children with CF usually didn't last past the age of kindergarten. Now, with all of the advances in medical research, we can proudly say that CF patients live much longer and have more productive lives, with the median age of 37. This is thanks in part to clinical trials which have brought effective new drug therapies to those with cystic fibrosis.

So in the next 2 to 3 years, we will need more than 7,000 CF patients to participate in clinical drug trials. Three thousand CF patients participated in trials last year. The bill we have here on the floor will help new therapies move quickly from the laboratory into the hands of the patients who need them and will reduce the administrative cost of disenrolling a beneficiary from SSI and Medicaid one month and reenrolling the beneficiary the very next month.

Importantly, the Congressional Budget Office has determined that this bill has very low real cost to the Federal Government, if none. So I ask my colleagues to join me in passage of this bill. As pointed out, we have over 120 cosponsors. The Association of Clinical Research Organizations has endorsed it, the Biotechnology Industry Organization, Cystic Fibrosis Foundation, Genetic Alliance, National Health Council, the National Organization of Rare Disorders, PhRMA, and Research!America.

Passage of this bill is a long time in coming. It will improve Americans' lives. As pointed out, it has no real cost. It is a simple fix to a current law that will save lives today. I urge its passage.

Mr. Speaker, I rise today in strong support of S. 1674—the Improving Access to Clinical Trials Act, or the I–ACT.

As the lead Republican sponsor of the original House version of this bill, H.R. 2866, I am so pleased we are taking up the companion to our bill that has already passed the Senate under unanimous consent. Passage of this bill in the House today will allow this important clinical trials legislation to be signed into law.

I am a proud co-chair and founder of the Congressional Cystic Fibrosis Caucus, along with my friend and colleague from Massachusetts, Mr. ED MARKEY. Through our work with the CF Caucus and the Cystic Fibrosis Foundation, we discovered that low income patients with rare diseases, such as cystic fibrosis, face a serious barrier to taking part in potentially lifesaving clinical trials, as the modest fee they receive for participating in a trial counts toward their eligibility for public health benefits such as Supplemental Security Income, SSI, and Medicaid. This actually forces patients to choose between receiving essential health benefits and the chance to participate in a clinical trial that could improve their condition. This is cruel choice no one should have to make.

Today there are approximately 30,000 people living in the U.S. with cystic fibrosis, and unfortunately almost half of the CF population receives public benefits, such as SSI and Medicaid. However, there are also over 30 new drug therapies and treatments for CF in the pipeline, more than in the entire history of CF research, that can improve the health and lives of CF patients and potentially lead us to a cure. Unfortunately, however, because CF is a rare disease, there just aren't enough CF patients who can participate in clinical trials because they are afraid of losing their public health benefits.

Our bill, the Improving Access to Clinical Trials Act, S.1674/H.R. 2866, will simply allow people with rare diseases like cystic fibrosis to participate in clinical trials that provide nominal compensation without the risk of losing their health care coverage.

Mr. Speaker, clinical trials are an essential part of the process as researchers develop treatments for diseases. When testing treatments for rare diseases in particular, researchers need a significant percent of the patient population for each disease to participate in these trials. And because of this, they often struggle to recruit enough participants.

For example, the University of Alabama at Birmingham houses one of the Cystic Fibrosis

Foundation's largest CF care centers with over 450 patients. UAB conducts numerous clinical trials on promising new treatments for CF patients, but when they began looking for CF patients to participate in a clinical trial for a new drug that some believe could be a game changer in the treatment of CF, they were only able to find 4 patients who met the trial protocol criteria. With these small numbers, the integrity of the study can be compromised if patients are not enrolled promptly. Enrollment becomes further compromised when patients choose to not participate because their SSI and Medicaid eligibility is at stake.

Mr. Speaker, we have come a long in treating CF. In the 1950's, children with CF usually didn't live past the age of kindergarten. Now, with all the advances in medical research, we can proudly say that CF patients live much longer and more productive lives, with a median age of 37. This is thanks in part to clinical trials that have brought effective new drug therapies to those with cystic fibrosis.

In the next 2–3 years, we will need more than 7,000 CF patients to participate in clinical drug trials. Three thousand CF patients participated in trials last year.

The I–ACT will help new therapies move quickly from the laboratory into the hands of the patients who need them and will also actually reduce the administrative costs of disenrolling a beneficiary from SSI and Medicaid one month and re-enrolling the beneficiary the next month. Importantly, the Congressional Budget Office has also determined that S. 1674 has no real costs to the Federal Government.

I ask my colleagues to join me in supporting S.1674—the Improving Access to Clinical Trials Act. The House version of this legislation enjoys strong bipartisan support, with 141 bipartisan cosponsors. And the Senate bill passed under unanimous consent on August 5, 2010.

Our bill has also been endorsed by over 120 organizations including: the Association of Clinical Research Organizations, the Biotechnology Industry Organization, the Cystic Fibrosis Foundation, Genetic Alliance, National Health Council, the National Organization of Rare Disorders, NORD, PhRMA, and Research!America.

Passage of this bill today will go a long way toward improving the lives of Americans with rare diseases, and to bringing us even closer to a cure for rare diseases. This legislation also has no real costs to the Federal Government. It's a simple fix to current law that will save lives, and I am proud to support this bill and be its lead Republican sponsor in the House.

Mr. MCDERMOTT. Mr. Speaker, I have no further requests for time, and I reserve the balance of my time.

Mr. BOUSTANY. Mr. Speaker, I am pleased to yield 3 minutes to the gentleman from Louisiana (Mr. FLEMING), a physician who knows a little bit about clinical trials.

Mr. FLEMING. I thank the gentleman from Louisiana for yielding me this time.

Mr. Speaker, I have two special investments in this bill, Improving Access to Clinical Trials Act. One is being a physician, a family physician for 34 years. The other is that I have a grandson who was born with cystic fibrosis almost a year to the day. He was born essentially clinically dead. His bowels, his colon had ruptured in utero as a result of his cystic fibrosis. He was delivered. It was an emergency delivery. He spent the first two months of his life in the NICU. Several times we thought we would lose him. He has had a rocky course since then. Today, as a child of a year old, he is catching up with all of his developmental milestones. His health is good, relatively speaking. And he is a beautiful young blessing to my family. He still has a very rocky course.

We know some of the statistics having to do with cystic fibrosis. There are approximately 30,000 people today with this disease. In the 1950s, children rarely lived beyond kindergarten with this disease. Today, the average age is 37. We see people even in their sixties with cystic fibrosis. More than 30 percent of the potential therapies that we have are in the CF drug development pipeline today, many wonderful therapies. We can even see over the horizon that we may some day have a cure within our lifetime.

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In the next 2 to 3 years, we will need more than 7,000 cystic fibrosis patients to participate in the clinical trials. So this problem that we have today with the fact that reimbursement from these clinical trials can ratchet down on one's SSI payments or Medicaid or Medicare is, of course, I think, a real impediment, a real blocking stone, for developments and strategies and therapies that we have for our clinical trials.

Again, Mr. Speaker, I stand with my colleagues today on both sides of the aisle for this very bipartisan bill that we support, the Improving Access to Clinical Trials Act, and I urge each and every one of my colleagues to vote in favor of it.

Mr. MCDERMOTT. Mr. Speaker, I reserve the balance of my time.

Mr. BOUSTANY. I am prepared to close.

Mr. Speaker, I just want to say that I am glad we can work together on this bipartisan bill. It is an important step in improving access to clinical trials.

I thank my colleague from Louisiana for sharing his personal story. It is a very poignant story, and it highlights the importance of this small step that we are taking to improve access to clinical trials.

Mr. KLEIN of Florida. Mr. Speaker, I rise today in strong support of the "Improving Access to Clinical Trials Act." I am a proud cosponsor of the House version because it will finally tear down an unnecessary barrier to clinical trials for people with life-threatening rare diseases like cystic fibrosis.

Under current law, patients with rare diseases face an unconscionable choice. If you are receiving Supplemental Security Income benefits, then you could potentially lose these benefits if you participate in a clinical trial. That's because many clinical trials offer compensation in accordance to ethical guidelines in exchange for your participation. This compensation can put you over the income requirements for the SSI program. So in effect, the choice becomes this: take a chance on a cure for tomorrow, or risk losing the critical support you depend on today. That's no choice that anyone should ever have to make.

The "Improving Access to Clinical Trials Act" removes this barrier by exempting the income from a clinical trial from the SSI threshold, thus freeing people to participate if they so choose. It's a common-sense fix that is long overdue and will help groundbreaking research into the cures of tomorrow for rare diseases.

I am also proud to support this legislation because one of my personal missions is to support research to fmd a cure for cystic fibrosis. Long before I ever came to Congress, my wife, Dori, and I supported the Cystic Fibrosis Foundation because of our close connection to people with this rare disease. Andrea Levy, from my hometown of Boca Raton, is one such person.

At the age of six, Andrea was diagnosed with cystic fibrosis. She has fought this disease with courage, and volunteers her time as an advocate for others that face similar health challenges. After graduating from the University of Florida with honors, she earned a masters' degree and is now working full-time as a counselor at a local school so she can continue to help others and give back to our community. Yet every day, she has to set aside hours for treatment and therapy to fight her disease. Andrea and the many others like her with CF should be able to live the American Dream without the burdens of a genetic disease. Yet this quirk in SSI law prevents more clinical trials from going forward because of a lack of people who will sign up.

It's for Andrea and all the people with rare diseases that I have pushed not only for greater access to clinical trials, but for greater investments in biomedical research. I am a longtime supporter of both the National Institutes of Health and private sector organizations such as The Scripps Research Institute and the Max Plank Institute. Finding cures to diseases that afflict so many must remain a fundamental goal of both the public and private sector. On this point, I will not waver.

Let me close by saying that the passage of this important legislation is a shining example of how this body should work. We have strong bipartisan support in both the House and the Senate. My good friend from Florida, Mr. STEARNS, has been a champion for cystic fibrosis and this legislation on the Republican side. I am proud to stand with him today and encourage our colleagues to support this important legislation and for President Obama to sign it into law.

Mr. BOUSTANY. Mr. Speaker, I yield back the balance of my time.

Mr. MCDERMOTT. Mr. Speaker, this is sort of an historic moment. If you can get three doctors to agree on the same thing on the floor of the House of Representatives, you've got a pretty good bill.

I urge passage of the bill, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Washington (Mr. MCDERMOTT) that the House suspend the rules and pass the bill, S. 1674.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

RENEWING AUTHORITY FOR STATE CHILD WELFARE DEMONSTRATION PROGRAMS

Mr. MCDERMOTT. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6156) to renew the authority of the Secretary of Health and Human Services to approve demonstration projects designed to test innovative strategies in State child welfare programs, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6156

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. RENEWAL OF AUTHORITY TO APPROVE DEMONSTRATION PROJECTS DESIGNED TO TEST INNOVATIVE STRATEGIES IN STATE CHILD WELFARE PROGRAMS.

Section 1130 of the Social Security Act (42 U.S.C. 1320a–9) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking ''1998 through 2003'' and inserting ''2011 through 2016'';

(B) in paragraph (3)—

(i) in subparagraph (A), by inserting ''or kinship guardianship'' after ''placements'';

(ii) in subparagraph (C), by striking ''address kinship care'' and inserting ''provide early intervention and crisis intervention services that safely reduce out-of-home placements and improve child outcomes''; and

(iii) by redesignating subparagraph (C) as subparagraph (D) and inserting after subparagraph (B) the following:

''(C) If an appropriate application therefor is submitted, the Secretary shall consider authorizing a demonstration project which is designed to identify and address domestic violence that endangers children and results in the placement of children in foster care.'';

(C) in paragraph (4), by inserting ''or kinship guardianship'' after ''assistance''; and

(D) in paragraph (5), by inserting ''and the ability of the State to implement a corrective action approved under section 1123A'' before the period;

(2) in subsection (e)—

(A) by striking ''and'' at the end of paragraph (6);

(B) by striking the period at the end of paragraph (7) and inserting ''; and''; and

(C) by adding at the end the following:

''(8) an accounting of any additional Federal, State, local, and private investments (other than those with respect to which matching funds were provided under part B or E of title IV) made, during the 2 fiscal years preceding the application to provide the services described in paragraph (1), and an assurance that the State will provide an accounting of that same spending for each year of an approved demonstration project.'';

(3) in subsection (f)(1)—

(A) in subparagraph (B), by striking ''; and'' and inserting '', including all children and families under the project who come to the attention of the State's child welfare program, either through a report of abuse or neglect or through the provision of services described in subsection (e)(1) to the child or family;''; and

(B) by redesignating subparagraph (C) as subparagraph (D) and inserting after subparagraph (B) the following:

''(C) a comparison of the amounts of Federal, State, local and private investments in the services described in subsection (e)(1), by service type, with the amount of the investments during the period of the demonstration project; and''; and

(4) by adding at the end the following:

''(h) INDIAN TRIBES CONSIDERED STATES.—An Indian tribe (as defined in section 479B(a)) shall be considered a State for purposes of this section.''.

SEC. 2. BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Washington (Mr. MCDERMOTT) and the gentleman from Georgia (Mr. LINDER) each will control 20 minutes.

The Chair recognizes the gentleman from Washington.

GENERAL LEAVE

Mr. MCDERMOTT. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and to include extraneous material on H.R. 6156.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Washington?

There was no objection.

Mr. MCDERMOTT. I yield myself such time as I may consume.

Mr. Speaker, the legislation before us today will help States test innovative approaches for improving outcomes for vulnerable children who come to the attention of our child welfare system.

The bill restores the authority of the Secretary of Health and Human Services to permit up to 10 demonstration projects annually to allow States and tribes to test efforts to improve child welfare policy. The legislation is cost neutral, and it provides the renewed waiver authority for the next 5 years.

To both increase our understanding of waiver policies and to ensure improved accountability, the legislation newly requires States to report the various sources of Federal, State, local, and private funds that are used in providing specific services under a demonstration project.

Finally, the bill adds a new Federal emphasis on supporting child welfare waivers that identify and address problems related to domestic violence that lead to children being placed in foster care and for waivers that provide early intervention and crisis intervention services that safely reduce out-of-home placements.

Past experience has taught us that child welfare waivers can help States improve outcomes for children while also informing child welfare policy at the national level. Twenty-three States received one or more waivers under the previous demonstration authority, which began in fiscal year 1996 and ended in March of 2006. Although the authority has expired, a handful of States continue to have demonstration projects in operation today.

One of the most successful strategies tested through the prior waiver authority was providing assistance to grandparents and other relatives who assume legal custody of children in foster care. Through the use of kinship care and guardianship assistance arrangements, children were able to find safe and loving homes with family members. This strategy proved to be successful in improving the outcomes of foster children, and it became Federal policy when it was incorporated into the Fostering Connections to Success and Increasing Adoptions Act, which was signed into law 2 years ago.

While providing waivers can be a useful tool in improving child welfare policy, we ultimately need more comprehensive changes to fully reform the system:

Waivers cannot correct certain basic flaws within our current method of financing child welfare programs, starting with the fact that increasing numbers of children are not eligible for Federal foster care assistance because of badly outdated eligibility criteria;

We also need systemic reforms which place a much greater emphasis on preventing abuse and neglect from occurring in the first place. I intend to continue to work towards broader reform to address these and other challenges facing programs serving children at risk of maltreatment.

Before I close, I want to quickly note that this bill continues a proud tradition of the Ways and Means Committee and of the Subcommittee on Income Security and Family Support of reporting out bipartisan legislation to improve our child welfare system.

During the last Congress, I worked with Representative Jerry Weller of Illinois to enact the Fostering Connections Act, which made a series of important changes to Federal policy related to children in foster care. It passed here by unanimous consent.

Today, I am joined by the ranking member of the subcommittee, Representative JOHN LINDER, in bringing this legislation to the floor; and I expect that it will also pass by unanimous consent. It has been a great pleasure to work with JOHN.

I know you are retiring, and I am going to have to work with a new subcommittee chairman one way or another, or with a ranking member.

So I am looking forward to continuing this tradition of dealing with the problems of children who need somebody to look out for them, and it should be a bipartisan issue every time.

I reserve the balance of my time.

Mr. LINDER. Mr. Chairman, thank you for your kind remarks.

I yield myself such time as I may consume.