shall be due 30 calendar days after publication of the notice provided for in section 744B(a)(2)(C)(i) of such Act.

(2) Notwithstanding section 744B(a)(3)(C)(ii) of such Act, the fee authorized under section 744B(a)(3) of such Act for fiscal year 2013 shall be due on the later of—

(A) the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies; or

(B) 30 calendar days after publication of the notice referred to in section 744B(a)(3)(B)(i) of such Act.

(3) Notwithstanding section 744B(a)(4)(D)(i) of such Act, the fee authorized under section 744B(a)(4) of such Act for fiscal year 2013 shall be due not later than 45 days after the publication of the notice under section 744B(a)(4)(C)(i) of such Act.

The bill was ordered to be engrossed and read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. UPTON. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials in the RECORD on this bill, H.R. 6433.

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

There was no objection.

NATIONAL PEDIATRIC RESEARCH NETWORK ACT OF 2012

Mr. UPTON. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6163) to amend title IV of the Public Health Service Act to provide for a National Pediatric Research Network, including with respect to pediatric rare diseases or conditions, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6163

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 ''National Pediatric Research Network Act of 2012''.

SEC. 2. NATIONAL PEDIATRIC RESEARCH NETWORK.

Section 409D of the Public Health Service Act (42 U.S.C. 284h; relating to the Pediatric Research Initiative) is amended—

(1) by redesignating subsection (d) as subsection (f); and

(2) by inserting after subsection (c) the following:

''(d) NATIONAL PEDIATRIC RESEARCH NETWORK.—

''(1) NETWORK.—In carrying out the Initiative, the Director of NIH, acting through the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research, may provide for the establishment of a National Pediatric Research Network consisting of the pediatric research consortia receiving awards under paragraph (2).

''(2) PEDIATRIC RESEARCH CONSORTIA.—

''(A) IN GENERAL.—The Director of the Institute may award funding, including through grants and contracts, to public or private nonprofit entities—

''(i) for planning, establishing, or strengthening pediatric research consortia; and

''(ii) for providing basic operating support for such consortia, including with respect to—

''(I) basic, clinical, behavioral, or translational research to meet unmet needs for pediatric research; and

''(II) training researchers in pediatric research techniques.

''(B) RESEARCH.—The Director of NIH shall ensure that—

''(i) each consortium receiving an award under subparagraph (A) conducts or supports at least one category of research described in subparagraph (A)(ii)(I) and collectively such consortia conduct or support all such categories of research; and

''(ii) one or more such consortia provide training described in subparagraph (A)(ii)(II).

''(C) NUMBER OF CONSORTIA.—The Director of NIH may make awards under this paragraph for not more than 20 pediatric research consortia.

''(D) ORGANIZATION OF CONSORTIUM.—Each consortium receiving an award under subparagraph (A) shall—

''(i) be formed from a collaboration of cooperating institutions;

''(ii) be coordinated by a lead institution; and

''(iii) meet such requirements as may be prescribed by the Director of NIH.

''(E) SUPPLEMENT, NOT SUPPLANT.—Any support received by a consortium under subparagraph (A) shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported under this paragraph.

''(F) DURATION OF SUPPORT.—Support of a consortium under subparagraph (A) may be for a period of not to exceed 5 years. Such period may be extended by the Director of NIH for additional periods of not more than 5 years.

''(3) COORDINATION OF CONSORTIA ACTIVITIES.—The Director of NIH shall—

''(A) as appropriate, provide for the coordination of activities (including the exchange of information and regular communication) among the consortia established pursuant to paragraph (2); and

''(B) require the periodic preparation and submission to the Director of reports on the activities of each such consortium.

''(e) RESEARCH ON PEDIATRIC RARE DISEASES OR CONDITIONS.—

''(1) IN GENERAL.—In making awards under subsection (d)(2) for pediatric research consortia, the Director of NIH shall ensure that an appropriate number of such awards are awarded to such consortia that agree to—

''(A) focus primarily on pediatric rare diseases or conditions (including any such diseases or conditions that are genetic disorders (such as spinal muscular atrophy and Duchenne muscular dystrophy) or are related to birth defects (such as Down syndrome and fragile X));

''(B) conduct or coordinate one or more multisite clinical trials of therapies for, or approaches to, the prevention, diagnosis, or treatment of one or more pediatric rare diseases or conditions; and

''(C) rapidly and efficiently disseminate scientific findings resulting from such trials.

''(2) DATA COORDINATING CENTER.—

''(A) ESTABLISHMENT.—In connection with support of consortia described in paragraph (1), the Director of NIH shall establish a data coordinating center for the following purposes:

''(i) To distribute the scientific findings referred to in paragraph (1)(C).

''(ii) To provide assistance in the design and conduct of collaborative research projects and the management, analysis, and storage of data associated with such projects.

''(iii) To organize and conduct multisite monitoring activities.

''(iv) To provide assistance to the Centers for Disease Control and Prevention in the establishment or expansion of patient registries and other surveillance systems.

''(B) REPORTING.—The Director of NIH shall—

''(i) require the data coordinating center established under subparagraph (A) to provide regular reports to the Director of NIH and the Commissioner of Food and Drugs on research conducted by consortia described in paragraph (1), including information on enrollment in clinical trials and the allocation of resources with respect to such research; and

''(ii) as appropriate, incorporate information reported under clause (i) into the Director's biennial reports under section 403.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. UPTON) and the gentlewoman from California (Mrs. CAPPS) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan.

Mr. UPTON. Mr. Speaker, I yield myself 3 minutes.

Mr. Speaker, this legislation brings us a step closer to providing more help to children with unmet health needs, especially those with rare pediatric and genetic diseases.

According to the National Institutes of Health, the NIH, there are 6,800 rare diseases, and most of these conditions have no treatment or cure, and they primarily affect children. I would guess that everyone in this Chamber is personally aware of the devastating impact of these diseases with some family that they know. I, myself, have spent some time with a family from my district whose children have spinal muscular atrophy, SMA. It is a very rare pediatric disease that is the leading genetic cause of death in infants and toddlers.

These are great kids. I've got a picture of one of them here. When they came to see me, they told me that their names were Cinderella and Sleeping Beauty. They really are. These are just really marvelous children. They're great kids, and it's a source of real sadness that their disease is the kind that is often incurable and often untreatable.

The barriers to research on rare and genetic diseases are those that are common to most research. It's already difficult to initiate the experimental and lengthy research needed to find treatments and cures; however, when the population of patients is so small, maybe only a couple dozen in a State, these problems are even more difficult to solve.

This legislation is going to help us establish pediatric research networks and a consortia that are a proven way to overcome those gaps in research. Networks and consortia will be comprised of leading institutions that act

as partners to consolidate and coordinate research efforts. It promotes efficiency and collaboration, especially when a disease affects just a small number of children.

Mr. Speaker, I would urge all my colleagues to support this bipartisan legislation. I look forward to a strong vote tonight and working with our colleagues in the Senate to make sure that this bill really does get to the President's desk and makes a difference for families that are in search of something that will help them with their kids.

With that, I reserve the balance of my time.

Mrs. CAPPS. Mr. Speaker, I yield myself 5 minutes.

Mr. Speaker, in the health care profession, we know that children aren't just little adults. They have unique health experiences, treatment needs, and research challenges.

While public and private research has come a long way on pediatric diseases over the years, we also know that we are still far behind on important diagnostics, cures, and treatments for far too many ailing children. That's why I am so pleased to have coauthored the National Pediatric Research Network Act with my colleague and friend, Representative CATHY MCMORRIS RODGERS.

This bipartisan bill would improve research and clinical trials on pediatric diseases. It would train future pediatric researchers and disseminate research findings so quickly so that all children may benefit. It does not replace our current pediatric research investments. Instead, it builds upon the work already being done at the NIH and at research centers across the country by creating, as Chairman UPTON said, research consortia to form a nationwide network of pediatric researchers. This is important so that we can make sure that we're always working with the most current science and that information is shared and also verified.

It will expand the geographic scope of research, giving sick kids easier access to research programs and clinical trials. Moreover, this bill will help a wider variety of institutions participating in this critical research while providing training grounds for our next generation of pediatric researchers.

Another key feature to this bill is that it will place an added emphasis on researching children's rare diseases, such as the one already described, spinal muscular atrophy, and to develop new treatments to fight them.

The low prevalence of these diseases makes them particularly hard to research, yet these diseases have such a marked impact on the lives of far too many families and communities. The National Pediatric Research Network Act will be an important step forward to help these families and those who may develop these diseases long into the future.

I want to thank again the leadership of the Energy and Commerce Committee, Chairman UPTON, Ranking Member WAXMAN, Chairman PITTS, and Ranking Member PALLONE, for their dedication to this bill; and to the staff, my staff, and especially Ruth Katz, a committee staffer, working to improve the language and to bring this to the floor. I also include my colleague, Congresswoman DEGETTE, for her leadership on this issue over the years.

And just like Chairman UPTON, I would especially like to thank my constituents, dear friends, and a very remarkable family, Bill and Victoria Strong, who are the parents, for their tireless work on behalf of their own daughter, Gwendolyn, who has spinal muscular atrophy as well and just a few weeks ago celebrated an amazing achievement by entering public kindergarten at the age of 5. She's the favorite of all her classmates, and the parents are beside themselves with joy that this remarkable milestone has been achieved. They work day in and day out to make their daughter's world better, and in doing so they have created a very strong community within our larger community of people who care about Gwendolyn, but also care about other children with similar kinds of conditions and what we should be doing as a Nation to stand with them. They have shown how entire communities can come together to fight diseases like SMA.

I urge my colleagues to follow their example. We need to come together now to support this bill, and in doing so we support families like those in Michigan and in Santa Barbara, California, and other places, as well, to do all we can do to make this a law and give them hope and courage for the future.

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

Mr. UPTON. Mr. Speaker, I yield myself 30 seconds.

I just want to again thank Mrs. CAPPS. As we met these families, we really did not know about these diseases until we saw their courage and what they do as they confront this every day. It's marvelous for me, as I now have visited my family that has this disease 2 years in a row. It's great to see them grow and remember where they were and to really think that there's going to be hope with the legislation that we can see that is done.

With that, I yield 5 minutes to the gentlelady from Washington State, CATHY MCMORRIS RODGERS, who has also been, as we look at a bipartisan leadership, a real trooper to move this legislation not only through our committee, but now on the House floor.

Mrs. MCMORRIS RODGERS. Mr. Speaker, I thank the chairman. I thank my colleague and friend, Representative LOIS CAPPS, and rise today in strong support of this legislation, H.R. 6163, the National Pediatric Research Network Act, which is going to build on America's commitment to pediatric medical research.

That commitment has already led to the prevention and treatment of terrible conditions such as polio, meningitis, childhood leukemia, congenital heart disease. With budgets being squeezed like no time in recent memory, it has never been more important to support projects which leverage every single dollar.

Research networks have a proven track record in their ability to ensure collaboration and the sharing of resources which, in turn, have led to medical discoveries that have improved lives.

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For example, the National Cancer Institute-funded Children's Oncology Group has advanced our understanding and treatment of childhood cancers, and this group has resulted in a cure for some types of childhood leukemia. The Pediatric Heart Network has improved the outcome for children born with congenital heart disease.

I am proud to have introduced this legislation with my colleague, Representative CAPPS. This legislation is going to authorize NIH to establish up to 20 pediatric research networks across this country, and each network will be selected by NIH through a competitive review process. These networks will allow multiple institutions to work together in a ''hub and spoke'' fashion to encourage collaboration.

Some of those networks will focus on rare diseases such as spinal muscular atrophy. Other networks will focus on the genetic diseases that have their onset in childhood, including Fragile X and Down Syndrome.

It's important to develop a framework for these rare and genetic diseases for a number of reasons. First of all, researchers in these areas are often working in isolation, and this legislation is going to help overcome that barrier. Secondly, there are not many children with these disorders in one place, so it makes it difficult to connect the researchers to those that want to participate in the studies.

Finally, the study of these rare and genetic diseases may lead to treatments that will help many people. For example, we've learned that there is a specific biological link between Down Syndrome and Alzheimer's disease. It's conceivable that the research that can result in the improvement in cognition in Down Syndrome could also prevent the loss of cognition that is seen in Alzheimer's.

These pediatric networks will improve health outcomes for children and adults by encouraging teamwork among the researchers, the patients, and NIH. This is important and positive legislation. I'm proud to support it, and I urge my colleagues to support it.

Mrs. CAPPS. In closing, Mr. Speaker, the National Pediatric Research Network Act is a very important bill, not just for current and future researchers, but for sick children and their families, today and in the future. It's a bipartisan measure that will really leverage

all the good work that is currently being done on pediatric diseases but that will also fill gaps that make it so hard for progress to be made.

I urge full support for this bill, and I yield back the balance of my time.

Mr. UPTON. Mr. Speaker, I yield 2 minutes to the chairman of the Health Subcommittee, the gentleman from Pennsylvania, JOE PITTS, in support of the legislation.

Mr. PITTS. Mr. Speaker, H.R. 6163, the National Pediatric Research Network Act, seeks to address important unmet needs in pediatric health.

Pediatric research is so important to the health of our children, and it is essential to finding answers for unmet health needs. According to the National Institutes for Health, there are between 6,000 and 7,000 diseases considered rare that affect 25 to 30 million people. Most of the approximately 7,000 rare diseases are pediatric diseases and often genetic. Unfortunately, the doctors do not have sufficient therapies to treat them.

This bill seeks to alleviate that problem by establishing pediatric research networks and consortia. They will help by coordinating research efforts among participating institutions, concentrating that effort on the most pressing needs and enlisting the help of well-trained researchers.

Through my association with Children's Hospital of Philadelphia, I'm aware that there are too many diseases that children and their families face that do not have easy answers, and few adequate treatments. This bill will strengthen basic and clinical research and bring us closer to finding new treatments and cures.

Mr. Speaker, this bill has strong bipartisan support. I urge my colleagues to support the bill.

Mr. UPTON. Mr. Speaker, in closing, I know the hour is late. I would just urge my colleagues to support this bipartisan legislation. I, too, commend every Member that's had a role here and truly appreciate the staff to get this bill prepared and ready for us to vote on tonight.

I yield back the balance of my time.

Mr. WAXMAN. Mr. Speaker, I am pleased to rise in support of H.R. 6163, the National Pediatric Research Network Act of 2012.

H.R. 6163 represents a bi-partisan effort to allow the National Institutes of Health, NIH, to establish a national pediatric research network dedicated to finding treatments and cures for pediatric diseases and conditions—especially those that are rare. The network would be comprised of up to 20 research consortia or groups of collaborating research institutions such as universities and hospitals. These consortia would be investigator-initiated and would conduct basic, clinical, behavioral, and translational research on pediatric diseases and conditions. NIH funding would be used to create the infrastructure necessary to carry out this research.

Within the network, the NIH Director is instructed to ensure that an appropriate number of awards go to those consortia that focus primarily on pediatric rare diseases such as spinal muscular atrophy—or SMA—or pediatric birth defects such as Down syndrome. These kinds of diseases and conditions are rare and some of the children who suffer from them are very fragile, making it difficult for them to travel great distances to participate in clinical trials or other research. This is often the case when—not infrequently—only one institution is conducting such research. The availability of consortia—by definition, multiple cooperating institutions—should make clinical research opportunities far more accessible to these kids and their families. In turn, we would hope they would help speed up the time and effort in finding treatments and cures for these devastating diseases and conditions.

In addition to the research itself, the consortia are expected to serve as training grounds for future pediatric researchers. Traditionally, pediatric research has been underfunded. This has sometimes resulted in real challenges in recruiting the talent necessary to tackle diseases and conditions that affect kids—again, especially those that are rare. Thus, H.R. 6163 places a special emphasis on pediatric research techniques with the goal of helping to ''prime the pump'' for a greater number of leading edge pediatric researchers.

Taken together, the components of H.R. 6163 make for a package that would allow NIH to build on the strong body of pediatric research that it currently conducts and supports. I would encourage NIH to take full advantage of this opportunity.

As we move forward with this legislation—here, and hopefully, in the Senate—I want to commend all those members of the Energy and Commerce Committee who have come together to make it happen. I especially want to the note the effort of Congresswoman CAPPS. She is the lead Democratic sponsor of the bill and has worked tirelessly to bring it before us today.

I urge my colleagues to vote ''yes'' on H.R. 6163.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Michigan (Mr. UPTON) that the House suspend the rules and pass the bill, H.R. 6163, as amended.

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

A motion to reconsider was laid on the table.

TAKING ESSENTIAL STEPS FOR TESTING ACT OF 2012

Mr. PITTS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6118) to amend section 353 of the Public Health Service Act with respect to suspension, revocation, and limitation of laboratory certification.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6118

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 ''Taking Essential Steps for Testing Act of 2012''.

SEC. 2. SUSPENSION, REVOCATION, AND LIMITATION OF LABORATORY CERTIFICATION.

Section 353 of the Public Health Service Act (42 U.S.C. 263a) is amended—

(1) in subsection (d)(1)(E), by inserting '', except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4)'' before the period at the end; and

(2) in subsection (i)—

(A) in paragraph (3), by inserting before the period at the end of the first sentence the following: '', except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph''; and

(B) in paragraph (4), by striking ''shall'' the first place it appears and inserting ''may''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Pennsylvania (Mr. PITTS) and the gentlewoman from California (Mrs. CAPPS) each will control 20 minutes.

The recognizes the gentleman from Pennsylvania.

GENERAL LEAVE

Mr. PITTS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials into the RECORD on H.R. 6118.

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

There was no objection.

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

Mr. Speaker, I rise today to support H.R. 6118, the Taking Essential Steps for Testing Act of 2012.

H.R. 6118 would give the Centers for Medicare and Medicaid Services much needed regulatory flexibility to enforce prohibitions against improper referrals of proficiency testing under the clinical laboratory improvement amendments.

In order to operate as a business, laboratories must adhere to CMS procedures for processing samples, must share testing results with CMS periodically and are prohibited from intentionally referring testing samples to any other lab.

Currently the Centers for Medicare and Medicaid Services is required under statute to revoke the CLIA certificate of any laboratory that intentionally refers its proficiency testing samples to another laboratory for testing for a period of 1 year.

In addition, the statute requires that a person who has owned or operated a laboratory which has had its CLIA certification revoked, including those owning multiple labs, may not own or operate a laboratory for a period of 2 years following such revocation.

However, there have been instances where a hospital or independent laboratory has accidently referred a PT sample to another lab due to mistakes by employees or through automated systems. In such instances CMS is not allowed by law to consider the circumstances under which the test was accidently referred or if the lab acted in good faith to report and address the incident.