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.

H.R. 6118 would address these issues by amending section 353 of the Public Health Service Act to allow the Secretary discretion to determine whether the 1-year ban on laboratories should be applied and the flexibility to levy immediate sanctions instead of the 2-year prohibition against ownership or operation of the lab.

The legislation enjoys bipartisan support among this body as well as numerous organizations, including the American Clinical Laboratory Association, the American Hospital Association, the College of American Pathologists, and the Clinical Laboratory Management Association, among others.

I would like to thank Congressman GRIMM and Congressman ROSKAM for their work on this legislation, and I urge Members to support the bill.

I reserve the balance of my time.

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

Mr. Speaker, the Taking Essential Steps for Testing Act is a bipartisan, sensible bill which will provide the Centers for Medicare and Medicaid Services the flexibility it needs in imposing penalties on clinical laboratories that violate certain recertification procedures. While not commonly discussed, the Clinical Laboratory Improvement Amendments of 1988, or CLIA, is an important law that ensures all labs operating in the United States can be trusted. Under CLIA, all labs must be certified to prove they are qualified to perform clinical tests while meeting quality and safety standards. We can all agree this is a good thing.

Labs are periodically retested to keep their CLIA certification. To do this, labs are required to perform proficiency tests which measure the quality and competency of a lab's work. Unlike some tests that come to a lab that can be sent out to other labs, proficiency tests must be performed in-house. Currently, if a lab is found to have referred a proficiency test to another lab, the Secretary of HHS must revoke that lab's certificate for at least 1 year. This prevents it from participating in Medicare or Medicaid for that period. In addition, the operator of any lab that has had its certificate revoked is barred from owning or operating any certified labs for 2 years.

However, current law does not allow the Secretary any flexibility in imposing these penalties for labs that improperly refer proficiency tests—even when it's an unintentional referral. This has led to labs that are being shut down across the country, potentially affecting patient care and access, even when their actions are not worthy of such a sanction. This is especially pronounced when the sanction occurs on just one lab that is part of a larger health care system, as the penalties apply to the entire system, even if all the other labs happen to be in compliance.

So this legislation would help address these problems by allowing CMS the flexibility to institute lesser sanctions to really address the problem instead of penalizing an entire system for unintentional proficiency test referrals. The bill does so without changing the accountability within the law or making our labs less reliable. And CMS still will be required and able to hold so-called ''bad actors'' accountable.

This bill is a very commonsense reform to CLIA, and I'm pleased to support it. I urge my colleagues to do so as well.

I reserve the balance of my time.

Mr. PITTS. Mr. Speaker, at this time I yield 4 minutes to the gentleman from New York (Mr. GRIMM).

Mr. GRIMM. Thank you for yielding me time.

Today, I rise in strong support of this legislation, H.R. 6118, the Taking Essential Steps for Testing Act. I would like to thank Chairman UPTON for his leadership, Ranking Member WAXMAN, as well as the Health Subcommittee and their entire staff for their support and dedication to this important bill.

The TEST Act is a bipartisan and bicameral solution to an issue that threatens Americans' access to health care. Under the Clinical Laboratory Improvement Amendments, CLIA, any lab that conducts human specimen testing must have a CLIA certificate and comply with the law's proficient testing, or PT, requirements. CLIA requires labs to treat PT samples as it would a patient sample. However, the law explicitly prohibits a lab from referring a PT sample to another laboratory, although this may be normal for patient procedures. The purpose of this prohibition is to ensure labs submit their own results for PT samples. I believe that this does clearly promote continued patient safety, accurate results, and that a lab is not getting reimbursed for tests it does not or cannot perform.

The concern is that labs which have accidentally referred a PT sample to another lab and self-reported this mistake are being told by CMS that CLIA does not provide any flexibility and therefore their certificates must be revoked. As a result, labs that make a mistake and proactively try to correct it are treated identically to labs that knowingly and in bad faith violate the law.

Without a CLIA certificate, as we have heard, labs are unable to conduct any human specimen testing. For hospitals, this could mean choosing between shutting down essentially all services such as the ER and the operating room or paying millions of dollars to bring in an outside lab for 2 years. Both of these options result in reduced access to health care and other related services for patients.

The TEST Act gives CMS discretion to not revoke a CLIA certificate for a PT referral if it is determined that the lab was acting in good faith. And for labs which are bad actors, the TEST Act does nothing to alter CMS's ability to punish those labs and revoke their certificate. H.R. 6118 also gives CMS the discretion to not apply the revocation to an entire hospital network or other owner-operators based on the facts of a particular case.

In determining whether or not to revoke a CLIA certificate, I urge CMS to consider factors such as the nature of the violation, the lab's history of compliance and past PT experience, whether or not the lab voluntarily reported the referral, any remedial actions taken by the lab, and any recommendations made by the State or applicable accrediting organization.

I would like to end by saying thank you to all of my colleagues that helped support this legislation and urge all my colleagues to vote in favor of H.R. 6118. It's commonsense legislation that ultimately puts patients first.

Mrs. CAPPS. May I ask the chairman if he has any other speakers?

Mr. PITTS. We have no further speakers.

Mrs. CAPPS. Mr. Speaker, in closing, the Taking Essential Steps for Testing Act is a straightforward bill with bipartisan support. It will give CMS tools to effectively deal with labs that unintentionally refer out their proficiency tests, maintain sanctions for labs that intentionally flaunt the law, and ensure that certified clinical labs are there for us when we need them.

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

Mr. PITTS. Mr. Speaker, I urge support for this commonsense, bipartisan bill, H.R. 6118, and I yield back the balance of my time.

Mr. WAXMAN. Mr. Speaker, I am pleased that we are taking up H.R. 6118, a bipartisan, non-controversial bill that will provide the Centers for Medicare & Medicaid Services (CMS) with additional flexibility in imposing and enforcing penalties on clinical laboratories under the Public Health Service Act.

The Committee on Energy and Commerce has a long history of being vigilant with respect to quality and safety standards for clinical laboratories. In fact, the Public Health Service Act standards for labs originated in this Committee when JOHN DINGELL, Ed Madigan, RON WYDEN and I sponsored the legislation in the 1980's.

All laboratories in the United States must be certified and meet certain quality and safety standards. To maintain certification, laboratories must periodically perform proficiency tests, which measure the quality of a lab's work. These proficiency tests must be performed in-house—as the test is intended to measure that specific lab's quality and competency.

If a lab is found to have intentionally referred a proficiency testing sample to another laboratory, the Secretary of HHS must revoke that lab's CLIA certificate for at least 1 year (thereby preventing it from billing Medicare or Medicaid for that period). In addition, the owner or operator of any lab that has had its CLIA certificate revoked is barred from owning or operating any CLIA-certified laboratory for 2 years.

Current law does not allow the Secretary any flexibility in imposing these penalties for

labs that improperly refer proficiency tests—even for an unintentional referral.

Equally importantly, there have been a number of changes in the organization and delivery of health care since these penalties provisions were enacted. In particular—the growth of health systems that have many providers joining together to operate under the same umbrella. In the case of laboratories, one hospital system may own and operate a number of labs. If one lab is found to have a proficiency testing violation, all of the labs under the hospital's system would be barred from Medicare—even if those labs had no quality or proficiency testing issues.

This is not a sensible result. This legislation would address that problem.

First, H.R. 6118 ensures the statute is clear on the point that no proficiency testing sample may be referred to another laboratory even if such referral would be part of the testing lab's standard procedure for patient specimens (a point of existing law on which some providers have been confused).

Second, it grants the Secretary discretion in determining whether to revoke a lab's CLIA certificate for improper referrals of PT testing samples—to account for the case of unintentional error.

Finally, the bill would grant the Secretary discretion to apply alternate sanctions in lieu of the 2-year owner/operator ban if a CLIA certificate has been revoked due to an improper proficiency testing referral, correcting the problem of having to ban all labs in a health system, even if the others had no known problems.

The Taking Essential Steps for Testing Act would address that issue, striking a balance to ensure quality protections remain, yet giving the Secretary the flexibility to more appropriately tailor penalties for violations of the law. I'm pleased to support this bill today.

Mr. UPTON. Mr. Speaker, H.R. 6118, the Taking Essential Steps for Testing (TEST) Act of 2012, is an important measure that grants CMS the necessary flexibility to enforce its rules without unnecessarily punishing employers for unintentional acts.

Under current law, laboratories must adhere to CMS procedures for processing testing samples in order to do business under the Clinical Laboratory Improvement Amendments (CLIA) law. In addition, they are prohibited from intentionally referring testing samples to other labs.

Unfortunately, CMS is not allowed to look at the circumstances under which labs refer samples, and must levy the same penalties for those operating in good faith as those knowingly and willfully breaking the law. These penalties include the loss of a lab's certification for a year and a prohibition against the owner operating any lab for a period of two years.

In instances where a hospital or independent laboratory has accidentally referred a sample due to mistakes by employees or through automated systems, these penalties can be needlessly harsh and threaten the livelihood of American workers. H.R. 6118 would address these issues by allowing the Secretary discretion when determining penalties.

The legislation has received bipartisan support among this body as well as numerous organizations. I would like to commend Congressmen GRIMM and ROSKAM for their work and urge Members to support its passage.

Mr. ROSKAM. Mr. Speaker, I rise today to express my support for H.R. 6118, the ''Taking Essential Steps for Testing Act of 2012'' or TEST Act. This legislation will give the Centers for Medicare and Medicaid (CMS) greater leeway when dealing with hospitals and laboratories across the nation.

Last year I was contacted by a hospital in my Congressional District who informed me that they had unintentionally referred a proficiency test to an outside lab because the lab technician was following patient procedure. They informed me that because of this error they would be forced to potentially close the lab and essentially fire the lab director. Upon further investigation, I was troubled to learn that the same problem was occurring across the country because CMS lacked the authority to handle these cases in any other fashion.

This is why I was happy to work with my good friend from New York, Mr. GRIMM, and Mr. ROSS from Arkansas, as well as Senators BOOZMAN, KLOBUCHAR, and SHAHEEN, to come up with a simple, commonsense solution to the problem. While working with CMS and our friends across the aisle, we were able to demonstrate that this institution is still capable of recognizing problems and pursuing solutions for the people we represent back home.

It is my hope that the Senate will quickly take up this legislation and send it to the President for signature so we can help provide regulatory relief to our nation's hospitals and labs.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Pennsylvania (Mr. PITTS) that the House suspend the rules and pass the bill, H.R. 6118.

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.

VETERAN EMERGENCY MEDICAL TECHNICIAN SUPPORT ACT OF 2012

Mr. PITTS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4124) to amend the Public Health Service Act to provide grants to States to streamline State requirements and procedures for veterans with military emergency medical training to become civilian emergency medical technicians, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4124

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 ''Veteran Emergency Medical Technician Support Act of 2012''.

SEC. 2. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO MEET REQUIREMENTS FOR BECOMING CIVILIAN EMERGENCY MEDICAL TECHNICIANS.

(a) IN GENERAL.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 314 the following:

''SEC. 315. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO MEET REQUIREMENTS FOR BECOMING CIVILIAN EMERGENCY MEDICAL TECHNICIANS.

''(a) PROGRAM.—The Secretary shall establish a program consisting of awarding demonstration grants to States to streamline State requirements and procedures in order to assist veterans who completed military emergency medical technician training while serving in the Armed Forces of the United States to meet certification, licensure, and other requirements applicable to becoming an emergency medical technician in the State.

''(b) USE OF FUNDS.—Amounts received as a demonstration grant under this section shall be used to prepare and implement a plan to streamline State requirements and procedures as described in subsection (a), including by—

''(1) determining the extent to which the requirements for the education, training, and skill level of emergency medical technicians in the State are equivalent to requirements for the education, training, and skill level of military emergency medical technicians; and

''(2) identifying methods, such as waivers, for military emergency medical technicians to forego or meet any such equivalent State requirements.

''(c) ELIGIBILITY.—To be eligible for a grant under this section, a State shall demonstrate that the State has a shortage of emergency medical technicians.

''(d) REPORT.—The Secretary shall submit to the Congress an annual report on the program under this section.

''(e) FUNDING.—Of the amount authorized by section 751(j)(1) to be appropriated to carry out section 751 for fiscal year 2013, there is authorized to be appropriated to carry out this section $1,000,000 for the period of fiscal years 2013 through 2017.''.

(b) CONFORMING AMENDMENT.—Section 751(j)(1) of the Public Health Service Act (42 U.S.C. 294a(j)(1)) is amended by striking ''There is authorized to be appropriated'' and inserting ''Subject to section 315(e), there is authorized to be appropriated''.

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 Chair 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 in the RECORD on H.R. 4124.

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 this evening in support of H.R. 4124, the Veteran Emergency Medical Technician Support Act of 2012. This act would take us forward