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

Mr. OBEY. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Evidently a quorum is not present.

The Sergeant at Arms will notify absent Members.

The vote was taken by electronic device, and there were—yeas 213, nays 190, not voting 30, as follows:

[Roll No. 663]

YEAS—213

Aderholt
Alexander
Bachus
Baker
Barrett (SC)
Bartlett (MD)
Bass
Beauprez
Biggert
Bilirakis
Bishop (UT)
Blackburn
Blunt
Boehlert
Boehner
Bonilla
Bonner
Bono
Boozman
Boustany
Bradley (NH)
Brady (TX)
Brown (SC)
Brown-Waite, Ginny
Burgess
Burton (IN)
Buyer
Calvert
Camp (MI)
Campbell (CA)
Cannon
Cantor
Capito
Carter
Castle
Chabot
Chocola
Coble
Cole (OK)
Conaway
Crenshaw
Culberson
Davis (KY)
Deal (GA)
DeLay
Dent
Diaz-Balart, L.
Doolittle
Drake
Dreier
Duncan
Emerson
English (PA)
Everett
Feeney
Ferguson
Fitzpatrick (PA)
Flake
Foley
Forbes
Fortenberry
Fossella
Foxx
Franks (AZ)
Frelinghuysen
Gallegly
Garrett (NJ)
Gerlach
Gibbons
Gillmor
Gingrey
Gohmert
Goode
Goodlatte
Granger
Graves
Green (WI)
Gutknecht
Hall
Harris
Hart
Hastings (WA)
Hayes
Hayworth
Hefley
Hensarling
Herger
Hobson
Hoekstra
Hostettler
Hulshof
Hunter
Inglis (SC)
Issa
Jenkins
Jindal
Johnson (CT)
Johnson (IL)
Johnson, Sam
Jones (NC)
Keller
Kelly
Kennedy (MN)
King (IA)
King (NY)
Kingston
Kirk
Kline
Knollenberg
Kuhl (NY)
LaHood
Latham
LaTourette
Leach
Lewis (CA)
Lewis (KY)
Linder
LoBiondo
Lucas
Lungren, Daniel E.
Mack
Manzullo
Marchant
McCaul (TX)
McCotter
McHenry
McHugh
McKeon
McMorris
Mica
Miller (FL)
Miller (MI)
Miller, Gary
Moran (KS)
Murphy
Musgrave
Neugebauer
Ney
Northup
Norwood
Nunes
Nussle
Osborne
Otter
Oxley
Paul
Pearce
Pence
Peterson (PA)
Petri
Pickering
Pitts
Poe
Pombo
Porter
Price (GA)
Pryce (OH)
Putnam
Radanovich
Ramstad
Regula
Rehberg
Reichert
Renzi
Reynolds
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Rothman
Royce
Ryan (WI)
Ryun (KS)
Saxton
Schmidt
Schwarz (MI)
Sensenbrenner
Sessions
Shadegg
Shaw
Shays
Sherwood
Shimkus
Shuster
Simmons
Simpson
Smith (NJ)
Smith (TX)
Sodrel
Souder
Sullivan
Sweeney
Tancredo
Taylor (NC)
Terry
Thomas
Thornberry
Tiahrt
Tiberi
Turner
Upton
Walden (OR)
Walsh
Wamp
Weldon (FL)
Weller
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Young (AK)

NAYS—190

Abercrombie
Ackerman
Allen
Andrews
Baird
Baldwin
Barrow
Bean
Berkley
Berman
Berry
Bishop (GA)
Bishop (NY)
Blumenauer
Boren
Boswell
Boucher
Boyd
Brady (PA)
Brown (OH)
Brown, Corrine
Butterfield
Capps
Capuano
Cardin
Carnahan
Carson
Case
Chandler
Cleaver
Clyburn
Conyers
Cooper
Costa
Costello
Cramer
Crowley
Cuellar
Davis (AL)
Davis (CA)
Davis (FL)
Davis (IL)
Davis (TN)
DeFazio
DeGette
Delahunt
DeLauro
Dicks
Dingell
Doggett
Doyle
Edwards
Emanuel
Engel
Eshoo
Etheridge
Evans
Farr
Fattah
Filner
Ford
Frank (MA)
Gonzalez
Gordon
Green, Al
Green, Gene
Grijalva
Gutierrez
Harman
Hastings (FL)
Herseth
Higgins
Hinchey
Hinojosa
Holden
Holt
Honda
Hooley
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson, E. B.
Jones (OH)
Kanjorski
Kaptur
Kennedy (RI)
Kildee
Kilpatrick (MI)
Kind
Kucinich
Langevin
Lantos
Larsen (WA)
Larson (CT)
Lee
Levin
Lewis (GA)
Lipinski
Lofgren, Zoe
Lowey
Lynch
Maloney
Markey
Marshall
Matheson
Matsui
McCollum (MN)
McDermott
McGovern
McIntyre
McKinney
McNulty
Meehan
Meek (FL)
Meeks (NY)
Melancon
Menendez
Michaud
Millender-McDonald
Miller (NC)
Miller, George
Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murtha
Nadler
Napolitano
Neal (MA)
Oberstar
Obey
Olver
Ortiz
Owens
Pallone
Pascrell
Payne
Pelosi
Peterson (MN)
Pomeroy
Price (NC)
Rahall
Rangel
Reyes
Ross
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Sabo
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sanders
Schakowsky
Schiff
Schwartz (PA)
Scott (GA)
Scott (VA)
Serrano
Sherman
Skelton
Slaughter
Smith (WA)
Snyder
Solis
Stark
Strickland
Stupak
Tanner
Tauscher
Taylor (MS)
Thompson (CA)
Thompson (MS)
Tierney
Towns
Udall (CO)
Udall (NM)
Van Hollen
Velázquez
Visclosky
Wasserman Schultz
Watt
Waxman
Weiner
Woolsey
Wu
Wynn

NOT VOTING—30

Akin
Baca
Barton (TX)
Becerra
Cardoza
Clay
Cubin
Cummings
Davis, Jo Ann
Davis, Tom
Diaz-Balart, M.
Ehlers
Gilchrest
Hoyer
Hyde
Istook
Kolbe
McCarthy
McCrery
Myrick
Pastor
Platts
Spratt
Stearns
Waters
Watson
Weldon (PA)
Westmoreland
Wexler
Young (FL)

□ 1518

Ms. HERSETH changed her vote from ''yea'' to ''nay.''

So the resolution, as amended, was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated for:

Mr. STEARNS. Mr. Speaker, on rollcall No. 663 I was unavoidably detained. Had I been present, I would have voted ''yes.''

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. MCHUGH). 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 is objected to under clause 6 of rule XX.

Record votes on postponed questions will be taken later today.

PROFICIENCY TESTING IMPROVEMENT ACT OF 2005

Mr. DEAL of Georgia. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4568) to improve proficiency testing of clinical laboratories, as amended.

The Clerk read as follows:

H.R. 4568

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 ''Proficiency Testing Improvement Act of 2005''.

SEC. 2. IMPROVEMENT OF PROFICIENCY TESTING OF CLINICAL LABORATORIES.

Notwithstanding any other provision of law, the Secretary of Health and Human Services—

(1) may not, during the one-year period beginning on the date of the enactment of this Act, conduct (or cause an entity with which the Secretary contracts to conduct) the proficiency testing referred to in section 353(f)(4)(B)(iv) of the Public Health Service Act (42 U.S.C. 263a(f)(4)(B)(iv));

(2) shall revise such proficiency testing (or cause such testing to be revised)—

(A) to reflect the collaborative clinical decision-making of laboratory personnel involved in screening or interpreting cytological preparations;

(B) to revise grading or scoring criteria to reflect current practice guidelines;

(C) to provide for such testing to be conducted no more often than every 2 years; and

(D) to make such other revisions to the standards for such testing as may be necessary to reflect changes in laboratory operations and practices since such standards were promulgated in 1992; and

(3) shall make the revisions required by paragraph (2) within one year after the date of the enactment of this Act and before resuming proficiency testing referred to in such section.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Georgia (Mr. DEAL) and the gentleman from Ohio (Mr. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from Georgia.

GENERAL LEAVE

Mr. DEAL of Georgia. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on the bill.

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

There was no objection.

Mr. DEAL of Georgia. Mr. Speaker, I yield myself such time as I may consume.

Each year, the licensed physicians and cytotechnologists who screen and interpret Pap tests save the lives of thousands of women by detecting the

earliest signs of cervical cancer, a common cancer in women. Without question, these professionals serve a vital role in the health care delivery system of this Nation, and we owe them our sincere admiration and appreciation for the services they perform.

However, our Federal bureaucracy has let these professionals and their patients down by neglecting to develop an effective and appropriate proficiency test for these individuals as required by the Clinical Laboratory Improvement Amendments of 1998, commonly referred to as CLIA. Instead, the Centers for Medicare and Medicaid Services have recently chosen to implement an outdated and flawed testing system that was finalized over 13 years ago.

This situation is unacceptable, and these professionals who are performing vital services deserve better.

And that is why I have introduced this legislation. H.R. 4568 will place a hold on the current CMS testing system and require that a new rule be developed that accomplishes the following four goals: First, to reflect the collaborative clinical decision-making of laboratory personnel involved in screening or interpreting cytological preparations; second, to revise grading or scoring criteria to reflect current practice guidelines; and, third, to provide for such testing to be conducted no more often than every 2 years; and, fourth, to make such revisions to the standards for such testing as may be necessary to reflect changes in the laboratory operations and practices since the standards were promulgated originally in 1992.

This is the least we can do for these professionals. And I want to thank my colleagues SUE MYRICK, TOM PRICE, JOHN SHIMKUS and SHERROD BROWN for joining me in sponsoring this legislation.

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

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume.

Joining my friend from Georgia, Mr. DEAL, I rise in support of H.R. 4568, the Proficiency Testing Improvement Act.

It makes perfect sense to take steps to ensure that women are receiving accurate results after they have had a Pap test. But it makes no sense to take false steps in that direction. Proficiency testing can be extremely useful, or it can make a bad situation worse. If the proficiency test itself is inaccurate, then both competence and incompetence get lost in the shuffle. It is almost worse than not knowing.

H.R. 4568 gives the Secretary of Health and Human Services authority to revise a 13-year-old regulation that CMS has only recently acted on. The regulation calls for a Federal program to test the proficiency of individual laboratory individuals who read Pap tests.

Since this rule was first proposed in 1992, significant advances, such as computer-assisted screening, location-guided screening, digital imaging, have made a positive impact on screening for cervical cancer.

The proficiency testing system embedded in the agency's rule has not been modified to reflect these significant advances. As a result, the system is rooted in outdated and obsolete medical standards and practices. In fact, the testing scheme adopted 13 years ago but just implemented by the Federal Government this year is based upon standards that go back to the late 1960s.

H.R. 4568 delays implementation of this testing program for 1 year so the agency can review and revise the program to reflect current medical practice. One can look at it from a quality perspective, a safety perspective, an access perspective or a fiscal perspective. From any of those angles, it is in no one's best interest to use the wrong test to evaluate proficiency. All they end up with are more questions.

I want to make clear the bill does not repeal this testing program. It simply puts the program on pause while the agency makes changes to reflect valid and up-to-date medicine and laboratory working conditions.

In September, I joined over 100 Members of the House, from both parties, in sending a letter to Secretary Leavitt, urging him to update the testing program before implementing it. The Secretary of HHS, for whatever reason, has not responded.

In February, the Clinical Laboratory Improvement Advisory Committee, which advises the Department of Health and Human Services, unanimously recommended that the agency revise and update this 13-year-old regulation; yet the agency continues to move forward with a January 1, 2006, implementation date.

If we are serious in this body about promoting quality health care, we should ensure that the Federal Government's regulations are keeping pace with 21st Century medicine. This bill will help do that. I urge my colleagues to support it.

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

Mr. DEAL of Georgia. Mr. Speaker, I yield 2 minutes to the gentleman from Illinois (Mr. SHIMKUS), a member of the Energy and Commerce Committee that has jurisdiction over this issue.

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

Mr. SHIMKUS. Mr. Speaker, I want to thank Chairman DEAL of the subcommittee for his work on this legislation, also Ranking Member BROWN, and I think they accurately have mentioned what this legislation does.

It wants to hold off these regulations that are decades old for new science and new technology and for safety and cost and efficiency and all those things.

I just want to take this time to thank Dr. James Miller, who runs a lab in Fayette County Hospital in Vandalia, Illinois, for always keeping me updated on issues facing the laboratory community.

In my district and across the country, we already have a shortage of medical lab technicians. These proficiency testing regulations would further reduce access to cytology services.

I urge my colleagues to support this legislation, H.R. 4568.

□ 1530

Mr. BROWN of Ohio. Mr. Speaker, I yield 3 minutes to the gentlewoman from South Dakota (Ms. HERSETH), who has been a terrific advocate for women's health in our country.

Ms. HERSETH. Mr. Speaker, I thank my friend from Ohio for yielding and for his long-standing commitment for health care issues facing this country.

Mr. Speaker, I rise today in support of H.R. 4568, the Proficiency Testing Improvement Act of 2005, because this legislation reflects a thoughtful compromise, and I am extremely pleased we are going to have an opportunity to address the underlying issues concerning the clinical laboratory proficiency testing regime currently being implemented by the Centers for Medicare and Medicaid Services.

As I toured laboratories in South Dakota earlier this year and discussed the proficiency test with pathologists in my State, it has become clear to me that the science and practice guidelines for cytology have advanced substantially in the 13 years since the initial design of the proficiency testing program.

I have serious concerns with the possibility of qualified physicians and lab personnel being penalized as a result of a test based on outdated standards, and I have concerns about the access problems this may create in rural areas.

The Clinical Laboratory Improvement Advisory Committee, which is charged with advising the Secretary of Health and Human Services on the standards governing clinical laboratories, has recommended that the Department of Health and Human Services revise the outdated regulation to reflect the advances in the practice of cytology.

When it became clear that Secretary Leavitt intended to proceed with the January 1 implementation date, as Mr. BROWN indicated, I joined with him and many others of this body to urge the Secretary to suspend the current testing program and make the necessary revisions to reflect the advances in science, technology and practice. But time grows short, and without any assurances that the flaws in the current regime will be addressed, it is necessary for us to act.

This legislation delays implementation of proficiency testing for 1 year to allow the Secretary to make the appropriate revisions and ensure a testing program that reflects medically and scientifically current standards for the

practice of cytology. This step is necessary to protect access to clinical laboratory services and to ensure the high quality of those services.

I want to express my sincere thanks to all those who have worked so hard in the last few weeks to bring this legislation to the floor before the end of the session. Ranking Members DINGELL and BROWN, Chairman DEAL, Mr. PRICE, have all been diligent and thoughtful throughout this process. And I also want to extend my thanks to Chairman BARTON for his flexibility and offer my prayers for his speedy recovery during the Christmas season.

I encourage my colleagues in the House to support H.R. 4568 and our colleagues in the Senate to act swiftly to pass this important legislation before we adjourn.

Mr. DEAL of Georgia. Mr. Speaker, I am pleased to yield 4 minutes to my colleague, the gentleman from Georgia (Mr. PRICE), and to thank him for his efforts in shepherding this bill to the floor today.

(Mr. PRICE of Georgia asked and was given permission to revise and extend his remarks.)

Mr. PRICE of Georgia. Mr. Speaker, first, I want to thank Chairman DEAL for his leadership on this issue and Chairman BARTON as well for allowing this to go forward and thank particularly Mr. BROWN and Ms. HERSETH and Mr. DINGELL for working together to make certain that this issue is brought forward before we go home for the holiday.

Any testing, any testing, for quality in health care, must recognize and be tailored to real-life situations and the actual practice of medicine. As a physician, I have a real concern about quality health care and about how often government decisions may adversely affect that care.

In our State of Georgia, as the chairman knows, 40 percent of the pathologists in our State no longer read Pap smears. They no longer read Pap smears. The reason is not that they forgot how to read Pap smears. The reason is that the liability, the risk for reading a Pap smear at this point is greater than the benefit that they can derive themselves, and it is not worth putting their families at that personal financial risk to do so. If we go ahead with current CMS policy, I fear all across this Nation, we will see the remainder of the pathologists will no longer be able to read Pap smears, and consequently, the quality of care will be further diminished.

The reason that this test that has been proposed to move forward is flawed is because the practice of pathology is a collegial practice. If a pathologist is reading a slide to determine a diagnosis and he or she may have a question about it, they do not simply put it aside and not do anything about it. They call over Dr. Smith or Dr. Jones or one of the other personnel and ask them, what do you think? And they come to a decision together. Sometimes they may even take the specimen, that slide and the specimen they have, to a professor, to a university nearby or to a seminar that is being held and get other opinions. It is a collegial practice.

The test that is on the books right now and being proposed to be implemented January 1 on a mandatory basis does not recognize any of the collegiality of the practice of pathology or medicine for that matter.

So I believe that any testing that ought to be approved must be approved by the specialty society. The College of American Pathologists has wonderful individuals, scientists, individuals who understand the practice of medicine and also understand the science, and they must, they must, approve any test before it goes forward.

I also believe that any test that would be of benefit to us as citizens and truly increase the quality of care would be a test that measured the quality of the facility which recognizes the collegiality of the practice of pathology, and not be necessarily physician-specific, because that does not recognize how these things are done.

So, this bill, I commend the chairman once again for bringing it forward. I believe it is a commonsense measure. It is a measure that, ultimately, I believe, will result in a better rule and a better ability of pathologists and other physicians across this Nation to practice. I urge adoption of this bill.

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

Mr. DEAL of Georgia. Mr. Speaker, I am pleased to yield 4 minutes to the gentleman from Florida (Mr. WELDON), a physician familiar with this issue.

(Mr. WELDON of Florida asked and was given permission to revise and extend his remarks.)

Mr. WELDON of Florida. Mr. Speaker, I thank the subcommittee chairman for his leadership on this issue.

I am not an OB/GYN, but as a general internist, I performed numerous Pap smears. I was not here in 1992 when this statute was put in place. If I had been, I would have voted against it. I do not think the Federal Government has any business being in this process.

I have to ask everybody in the Chamber a question: Why do we want to have a special test only for the pathologists? Why not a Federal test for the doctor performing the Pap smear? I frequently did breast exams at the same time. Why not a special test, a Federal test, for that? What about the mammogram? Why not a Federal exam for a mammogram?

We obviously do not do that for obvious reasons. Professional societies govern these issues. State statutes govern them, and this is just a huge area.

Physicians of various specialties perform a multitude of different tests. They review and do a multitude of different procedures, and it would virtually be impossible; it would involve a colossal expansion of the Federal Government into essentially an area traditionally of commerce.

Now, understanding, as I do, that this is in the law, another reason why this is a bad law is just the way it has played out. Thirteen years for the regulatory agency to finally bring regulations to the process, to put them forward, and, lo and behold, surprise, surprise, they are completely outdated. They are completely inconsistent with what has been going on.

Litigation forces and the College of American Pathology's policies have changed the landscape, and now you essentially have many pathologists, as my physician colleague Dr. Price said earlier, and I commend him for his leadership on this, many pathologists have abandoned this. And you literally have certain pathologists who are specializing in this. They read them all the time. They go to seminars all the time. When they get difficult smears, they take them to the university. They bring their colleagues in the room.

To me, this is a wasteful and inappropriate involvement of the Federal Government, and I am very, very pleased that the other side of the aisle is willing to go along with this 1-year delay. Hopefully, the Senate will approve this.

What I hope is, ultimately, we repeal this, because I believe it is completely unnecessary, and it is inserting the Federal Government in a place that I do not think the American public would really want us to be, and that is into the details of the practice of medicine, carving out one specific area of pathology. Why are we not credentialing pathologists who read thyroid biopsies? That can be very, very important. What about breast biopsies? So to single this out, to me it is almost bizarre.

Mr. Speaker, I commend the chairman of the subcommittee. I am certainly looking forward to working with him in the year ahead. I certainly commend the ranking member for his willingness to allow this to move forward, and I do hope the Senate concurs, and we are able to pass this.

WHAT THE BILL DOES?

In 1992 CMS, HCFA, proposed regulations that would require proficiency testing of pathology labs for pap tests.

Those regs sat on the shelf for the past 13 years, until earlier this year CMS decided to implement these 13-year-old regs.

This bill simply delays for one more year the implementation of these regulations and asks CMS to update their regulations to reflect the practice of medicine today both within the pathology labs and in how clinicians respond to those lab tests.

WHY IS THIS BILL NECESSARY?

CMS dusted off 13-year-old regs that do not reflect the current practice of medicine.

CMS is requiring that pathologists examine these test exams in a vacuum; however, pathologists and cytologist practice in a team today. The CMS regulations don't reflect this change in practice; they are testing in a manner that does not reflect how a pathology is practiced today.

The test asks pathologists/cytologists to distinguish between high- and low-grade lesions.

In 1992 the standard of practice for low-grade lesions was to continue repeat cytology testing while colposcoply and biopsy were ordered for high-grade lesions.

The standard of practice today is to order colposcopy and biopsy for both high- and low-grade lesions.

The exam also applies a double standard for scoring—one test for cytologists and another higher standard for pathologists.

WHO HAS ASKED CMS TO DELAY THESE REGS

Ten national pathology and cytology organizations; 49 State pathology medical societies; over 120 Members of Congress wrote CMS in October asking CMS to delay this testing; even CMS's own Clinical Laboratory Improvement Advisory Committee, CLIAC, unanimously moved that CMS revise the cytology PT regulations to reflect current practice, evidence based guidelines and antipated changes in technology.

CONCLUSION

This bill will provide for only a 1-year delay of these regulations so that CMS can update the regulations that they left sitting on the shelf for the past 13 years.

Mr. BROWN of Ohio. Mr. Speaker, I yield 3 minutes to the gentleman from Maryland (Mr. CUMMINGS).

Mr. CUMMINGS. Mr. Speaker, I was just listening to the last speaker, and I just wanted to bring something to the attention of the House.

In Maryland, we had a situation where we had Maryland General Hospital, which is in my district, as a matter of fact, within 6 blocks of my house, and one of the things that we discovered was that the hospital was providing tests whereby personnel in the hospital knew that these HIV and hepatitis tests, the results were the wrong results. In other words, there was some faulty machinery. There was some problem within the lab itself. And when the whistleblower went to blow the whistle, the whistleblower was fired.

Government does have a role in this. The government must have a role. Almost, not almost, every single person in this country at some point is subjected to some type of medical test. As a matter of fact, we in the State of Maryland, it was of such significance that we got the College of American Pathologists to revise their entire program so as to protect whistleblowers, to make sure that if there was retaliation against a whistleblower, that that clinical lab could lose its accreditation.

They also are spending $9 million over the next 2 years to revamp their whole process, because here is the College of American Pathologists who oversees some 6,000 clinical labs all around the world, and they realized that it was important that they give proper results and protect whistleblowers, have a better system. But I can tell you the thing that pushed them to do that was government intervention.

So I understand this particular piece of legislation. I think it makes sense. I wish we had a little bit more time to consider it. The fact is, I am not going to stand in the way of it, but I refuse to accept an argument that says that government has no role in this, because, again, the American public must, must, have confidence in medical tests, must be able to rely on them.

When we are talking about such subjects as medical malpractice, Mr. Speaker, if someone has the wrong results on a test, my God, it may result in all kinds of very unfortunate circumstances and expenses and pain and suffering to a family.

Mr. DEAL of Georgia. Mr. Speaker, I yield myself 15 seconds just to respond to the gentleman and assure him that we understand his concerns with the whistleblower, but this is a situation in which government does have a role, but we are trying to make sure that government does not impose outdated regulations that are 13 years old and do not associate themselves with the current realities of the practice.

Mr. Speaker, I yield 2 minutes to the gentleman from Pennsylvania (Mr. SHUSTER).

Mr. SHUSTER. Mr. Speaker, I thank the gentleman for yielding me the time.

Mr. Speaker, I rise today in support of H.R. 4568. This legislation will put in place a 1-year delay of a problematic cytology testing program and will allow HHS to review and revise the program in order to better reflect current medical practice.

Numerous pathologists from my district in central and western Pennsylvania have expressed great concern over this testing program. I would like to share a portion of a letter I received from a well-respected pathologist from Roaring Springs, Pennsylvania, Dr. Bill Kirsch, regarding this issue. And I think it is extremely important to hear the words of a practicing pathologist and not just legislators on the floor of the House.

Dr. Kirsch first contacted me in August of this year saying the following:

''Although I have not received the survey material at this time, it was apparent when I read the initial introduction of this new testing procedure that it had little merit and was only vaguely related to the actual practice of cytopathology.

''My contention is this supposed proficiency examination will do little or nothing to improve the quality of the cytopathology services and only add to hospital expenses through fee and the paid time for the cytology tech staff and the pathologist forced to participate. There are other proficiency tests that I have subscribed to for a number of years and have helped me to become a better cytopathologist.

''The current proficiency testing by MIME has, in my opinion, no merit and does not deserve to be continued. It does not have the support of pathology or cytopathologist professionals and should not have even been initiated.''

Mr. Speaker, I respect the wisdom and experience of many of the doctors and laboratory professionals that have contacted me asking that we please ask HHS to step back and review this testing program. A vote for the commonsense legislation is just what the doctor ordered.

□ 1545

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

Mr. DEAL of Georgia. Mr. Speaker, I yield 2 minutes to the gentleman from Texas (Mr. BURGESS), my colleague on the Health Subcommittee of Energy and Commerce.

Mr. BURGESS. Mr. Speaker, I thank the chairman and the ranking member for bringing this relevant and important piece of legislation to the floor today.

It is probably the cervical cytology that has been more responsible than any other medical test for the foundation of preventative medicine in the United States.

I cannot tell you of the change that has taken place in the science of cervical cytologies from 1988, when this language was first written, until the time I left practice in 2002. The change has been so rapid in the science of cytology; and the language in this legislation being over 10 years old, over a decade old, is inappropriate for the 21st century.

In this day and time, we now have thin-layer cytologies. We have liquid-based cytologies, none of which were available in the late 80s or early 90s. The accuracy of these tests is light years ahead of what it was. If you add to that the ability to do DNA typing on abnormal cells, a lot of problems with false negatives have been eliminated. The CLIA standards to affect this language at this point would be inappropriate. They would be draconian. In fact, they would be a big step backward.

I look forward to working with my chairman. I look forward to working with the committee with my fellow members to develop language that more accurately measures the performance of cytopathologists and pathologists.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I was just looking through the CMS informational supplement on this whole issue, and I just wanted to read the reason that CMS could not get its act together through Secretary Thompson and now Secretary Leavitt, that they have delayed this so much longer than it needed to, and this is their sort of double speak, if you will:

''Implementation of cytology proficiency testing has taken an extended period of time due to the absence of qualified national proficiency testing organizations and insufficient number of reference cytology testing materials and significant technical difficulties. Currently, there are two CMS-approved cytology proficiency testing programs in the country for 2005, and we anticipate the approval of additional programs in 2006.''

So the last 5 years both Secretary Thompson and Secretary Leavitt have not been able to get this whole program up and running. Now we have this same cast of characters telling the country that we have got to implement the Medicare bill right now when plenty of people in this body, led by Ms. SCHAKOWSKY of Illinois and Mr. STARK from California, it said on the Medicare bill that we should push back the deadline for people who want to benefit from the Medicare prescription drug benefit program, who want to benefit but cannot yet make their minds up because of the complexity of it. And they will be actually financially penalized if they do not make that decision more quickly than many seniors feel that they are capable of making.

At the same time, we are also doing nothing to allow the Secretary of CMS to bring down the price of prescription drugs. In fact, this institution, this body, prohibited the government from negotiating lower prices. So while Secretary Thompson and now Secretary Leavitt could not get their act together on this, they seem to want to move forward too quickly on Medicare, forcing seniors to make a choice prematurely in the minds of many seniors or pay an economic financial penalty for every month they delay, and at the same time doing nothing to bring the price of prescription drugs down.

It all fits together in a peculiar way, Mr. Speaker. That does not mean this bill is not important. I join my colleague, Mr. DEAL, in support of it. As always, there is a little bigger picture here.

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

Mr. DEAL of Georgia. Mr. Speaker, I yield myself such time as I may consume.

While my colleague, Mr. BROWN of Ohio, is my copartner in the issue of health care and he and I share many things in common, this bill being one of them, and I would disagree with his comments with regard to Medicare part D, I for one am pleased that we are finally offering senior citizens of this country the opportunity to have a prescription drug benefit plan.

We can disagree on that, and we will probably have some disagreements in the future; but I do want to thank Mr. BROWN of Ohio and his staff and the others on the minority side for their cooperation in dealing with this issue that is before us today on pathology licensure.

I think that it is a bill that we need to act on quickly, and hopefully our colleagues across the way will do likewise.

Mr. DINGELL. Mr. Speaker, I support H.R. 4568, the "Proficiency Testing Improvement Act of 2005," which requires the Secretary of the Department of Health and Human Services to update the federal program to test the proficiency of individual laboratory professionals who read Pap tests. This bill delays implementation of the program first proposed in 1992 so that revisions, including those recommended by the Clinical Laboratory Improvement Advisory Committee, can be made. Importantly, these revisions are required to be made within one year, and must be made before proficiency testing can resume.

This is a commonsense measure that will assure that regulations implemented by the Federal Government reflect current science, technology, and medical practice. I urge my colleagues to support it.

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

The SPEAKER pro tempore (Mr. MCHUGH). The question is on the motion offered by the gentleman from Georgia (Mr. DEAL) that the House suspend the rules and pass the bill, H.R. 4568.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

STEM CELL THERAPEUTIC AND RESEARCH ACT OF 2005

Mr. DEAL of Georgia. Mr. Speaker, I move to suspend the rules and concur in the Senate amendment to the bill (H.R. 2520) to provide for the collection and maintenance of human cord blood stem cells for the treatment of patients and research, and to amend the Public Health Service Act to authorize the C.W. Bill Young Cell Transplantation Program.

The Clerk read as follows:

Senate amendment:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stem Cell Therapeutic and Research Act of 2005''.

SEC. 2. CORD BLOOD INVENTORY.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into one-time contracts with qualified cord blood banks to assist in the collection and maintenance of 150,000 new units of high-quality cord blood to be made available for transplantation through the C.W. Bill Young Cell Transplantation Program and to carry out the requirements of subsection (b).

(b) REQUIREMENTS.—The Secretary shall require each recipient of a contract under this section—

(1) to acquire, tissue-type, test, cryopreserve, and store donated units of cord blood acquired with the informed consent of the donor, as determined by the Secretary pursuant to section 379(c) of the Public Health Service Act, in a manner that complies with applicable Federal and State regulations;

(2) to encourage donation from a genetically diverse population;

(3) to make cord blood units that are collected pursuant to this section or otherwise and meet all applicable Federal standards available to transplant centers for transplantation;

(4) to make cord blood units that are collected, but not appropriate for clinical use, available for peer-reviewed research;

(5) to make data available, as required by the Secretary and consistent with section 379(d)(3) of the Public Health Service Act (42 U.S.C. 274k(d)(3)), as amended by this Act, in a standardized electronic format, as determined by the Secretary, for the C.W. Bill Young Cell Transplantation Program; and

(6) to submit data in a standardized electronic format for inclusion in the stem cell therapeutic outcomes database maintained under section 379A of the Public Health Service Act, as amended by this Act.

(c) RELATED CORD BLOOD DONORS.—

(1) IN GENERAL.—The Secretary shall establish a 3-year demonstration project under which qualified cord blood banks receiving a contract under this section may use a portion of the funding under such contract for the collection and storage of cord blood units for a family where a first-degree relative has been diagnosed with a condition that will benefit from transplantation (including selected blood disorders, malignancies, metabolic storage disorders, hemoglobinopathies, and congenital immunodeficiencies) at no cost to such family. Qualified cord blood banks collecting cord blood units under this paragraph shall comply with the requirements of paragraphs (1), (2), (3), and (5) of subsection (b).

(2) AVAILABILITY.—Qualified cord blood banks that are operating a program under paragraph (1) shall provide assurances that the cord blood units in such banks will be available for directed transplantation until such time that the cord blood unit is released for transplantation or is transferred by the family to the C.W. Bill Young Cell Transplantation Program in accordance with guidance or regulations promulgated by the Secretary.

(3) INVENTORY.—Cord blood units collected through the program under this section shall not be counted toward the 150,000 inventory goal under the C.W. Bill Young Cell Transplantation Program.

(4) REPORT.—Not later than 90 days after the date on which the project under paragraph (1) is terminated by the Secretary, the Secretary shall submit to Congress a report on the outcomes of the project that shall include the recommendations of the Secretary with respect to the continuation of such project.

(d) APPLICATION.—To seek to enter into a contract under this section, a qualified cord blood bank shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require. At a minimum, an application for a contract under this section shall include a requirement that the applicant—

(1) will participate in the C.W. Bill Young Cell Transplantation Program for a period of at least 10 years;

(2) will make cord blood units collected pursuant to this section available through the C.W. Bill Young Cell Transplantation Program in perpetuity or for such time as determined viable by the Secretary; and

(3) if the Secretary determines through an assessment, or through petition by the applicant, that a cord blood bank is no longer operational or does not meet the requirements of section 379(d)(4) of the Public Health Service Act (as added by this Act) and as a result may not distribute the units, transfer the units collected pursuant to this section to another qualified cord blood bank approved by the Secretary to ensure continued availability of cord blood units.

(e) DURATION OF CONTRACTS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the term of each contract entered into by the Secretary under this section shall be for 10 years. The Secretary shall ensure that no Federal funds shall be obligated under any such contract after the earlier of—

(A) the date that is 3 years after the date on which the contract is entered into; or

(B) September 30, 2010.

(2) EXTENSIONS.—Subject to paragraph (1)(B), the Secretary may extend the period of funding under a contract under this section to exceed a period of 3 years if—

(A) the Secretary finds that 150,000 new units of high-quality cord blood have not yet been collected pursuant to this section; and

(B) the Secretary does not receive an application for a contract under this section from any