

# RE-REFERRAL OF S. 3560 TO COMMITTEE ON ENERGY AND COMMERCE AND COMMITTEE ON WAYS AND MEANS

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that the bill, S. 3560, be re-referred to the Committee on Energy and Commerce and, in addition, to the Committee on Ways and Means.

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

There was no objection.

## QI PROGRAM SUPPLEMENTAL FUNDING ACT OF 2008

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 3560) to amend title XIX of the Social Security Act to provide additional funds for the qualifying individual (QI) program, and for other purposes.

The Clerk read the title of the Senate bill.

The text of the Senate bill is as follows:

S. 3560

*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 "QI Program Supplemental Funding Act of 2008".

### SEC. 2. FUNDING FOR THE QUALIFYING INDIVIDUAL (QI) PROGRAM.

Section 1933(g)(2) of the Social Security Act (42 U.S.C. 1396u-3(g)(2)), as amended by section 111(b) of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110-275), is amended—

(1) in subparagraph (I), by striking "\$300,000,000" and inserting "\$315,000,000"; and

(2) in subparagraph (J), by striking "\$100,000,000" and inserting "\$130,000,000".

### SEC. 3. MANDATORY USE OF STATE PUBLIC ASSISTANCE REPORTING INFORMATION SYSTEM (PARIS) PROJECT.

(a) IN GENERAL.—Section 1903(r) of the Social Security Act (42 U.S.C. 1396b(r)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A), by inserting ", in addition to meeting the requirements of paragraph (3)," after "a State must"; and

(2) by adding at the end the following new paragraph:

"(3) In order to meet the requirements of this paragraph, a State must have in operation an eligibility determination system which provides for data matching through the Public Assistance Reporting Information System (PARIS) facilitated by the Secretary (or any successor system), including matching with medical assistance programs operated by other States."

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by subsection (a) take effect on October 1, 2009.

(2) EXTENSION OF EFFECTIVE DATE FOR STATE LAW AMENDMENT.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) which the Secretary of Health and Human Services determines requires State legislation in order for the plan to meet the additional requirements imposed by the amendments made by subsection (a), the State plan shall not be regarded as failing to comply with the require-

ments of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

### SEC. 4. INCENTIVES FOR THE DEVELOPMENT OF, AND ACCESS TO, CERTAIN ANTIBIOTICS.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(v) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

"(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

"(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

"(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

"(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

"(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

"(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

"(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

"(i) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

"(ii) the 5-year exclusivity period referred to under clause (i) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

"(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

"(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

"(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

"(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

"(3) LIMITATIONS.—

"(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

"(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of the enactment of this subsection.

"(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A)."

(b) TRANSITIONAL RULES.—

(1) With respect to a patent issued on or before the date of the enactment of this Act, any patent information required to be filed with the Secretary of Health and Human Services under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to be listed on a drug to which subsection (v)(1) of such section 505 (as added by this section) applies shall be filed with the Secretary not later than 60 days after the date of the enactment of this Act.

(2) With respect to any patent information referred to in paragraph (1) of this subsection that is filed with the Secretary within the 60-day period after the date of the enactment of this Act, the Secretary shall publish such information in the electronic version of the list referred to at section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) as soon as it is received, but in no event later than the date that is 90 days after the enactment of this Act.

(3) With respect to any patent information referred to in paragraph (1) that is filed with the Secretary within the 60-day period after the date of enactment of this Act, each applicant that, not later than 120 days after the date of the enactment of this Act, amends an application that is, on or before the date of the enactment of this Act, a substantially complete application (as defined in paragraph (5)(B)(iv) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j))) to contain a certification described in paragraph (2)(A)(vi)(IV) of such section 505(j) with respect to that patent shall be deemed to be a first applicant (as defined in paragraph (5)(B)(iv) of such section 505(j)).

### SEC. 5. CLARIFICATION OF AUTHORITY FOR USE OF MEDICAID INTEGRITY PROGRAM FUNDS.

(a) CLARIFICATION OF AUTHORITY FOR USE OF FUNDS.—

(1) IN GENERAL.—Section 1936 of the Social Security Act (42 U.S.C. 1396u-6) is amended—

(A) in subsection (b)(4), by striking "Education of" and inserting "Education or training, including at such national, State, or regional conferences as the Secretary may establish, of State or local officers, employees, or independent contractors responsible for the administration or the supervision of the administration of the State plan under this title,"; and

(B) in subsection (e), by striking paragraph (2) and inserting the following:

"(2) AVAILABILITY; AUTHORITY FOR USE OF FUNDS.—

"(A) AVAILABILITY.—Amounts appropriated pursuant to paragraph (1) shall remain available until expended.

“(B) AUTHORITY FOR USE OF FUNDS FOR TRANSPORTATION AND TRAVEL EXPENSES FOR ATTENDEES AT EDUCATION, TRAINING, OR CONSULTATIVE ACTIVITIES.—

“(i) IN GENERAL.—The Secretary may use amounts appropriated pursuant to paragraph (1) to pay for transportation and the travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business, of individuals described in subsection (b)(4) who attend education, training, or consultative activities conducted under the authority of that subsection.”.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect as if included in the enactment of section 1936 of the Social Security Act, as added by section 6034(a) of the Deficit Reduction Act of 2005 (Public Law 109-171).

(b) PUBLIC DISCLOSURE.—

(1) IN GENERAL.—Section 1936(e)(2)(B) of such Act (42 U.S.C. 1396u-6(e)(2)(B)), as added by subsection (a) of this section, is amended by adding at the end the following:

“(ii) PUBLIC DISCLOSURE.—The Secretary shall make available on a website of the Centers for Medicare & Medicaid Services that is accessible to the public—

“(I) the total amount of funds expended for each conference conducted under the authority of subsection (b)(4); and

“(II) the amount of funds expended for each such conference that were for transportation and for travel expenses.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to conferences conducted under the authority of section 1936(b)(4) of the Social Security Act (42 U.S.C. 1396u-6(b)(4)) after the date of enactment of this Act.

#### SEC. 6. FUNDING FOR THE MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking “\$2,220,000,000” and inserting “\$2,290,000,000”.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Oklahoma (Mr. SULLIVAN) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

#### GENERAL LEAVE

Mr. PALLONE. Mr. Speaker I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and include extraneous material on the bill under consideration.

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

There was no objection.

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

Mr. Speaker, I rise in strong support of S. 3560, the QI Program Supplemental Funding Act of 2008, introduced by my Senate colleague, Senator MAX BAUCUS.

Mr. Speaker, this bill makes a number of technical, but important, changes that will improve the Medicare and Medicaid programs. This legislation also contains an important provision that will help incentivize the development of new antibiotics.

Earlier this summer, Congress passed H.R. 6331, the Medicare Improvements

for Patients and Providers Act of 2008, which extended the Qualifying Individual, or QI, program to December of 2009. The QI program provides important financial assistance to low-income Medicare beneficiaries.

Unfortunately, when we passed H.R. 6331, we did not include enough money in the QI program to fully cover the level of need. We need an additional \$45 million in order to fully cover the cost of the program through the end of next year. Otherwise, vulnerable Medicare beneficiaries may be disenrolled and lose access to important health services, and we certainly can't allow this to happen.

Mr. Speaker, this legislation also contains a provision that would encourage and incentivize drug manufacturers to research and develop antibiotics. Presently, there's too little research being done to develop new and innovative antibiotics therapies. That is particularly troubling at a time when antibiotic resistance is a growing problem.

According to the Infectious Disease Society of America, about 2 million people acquire bacterial infections in U.S. hospitals each year, and 90,000 die as a result. Approximately 70 percent of these infections are resistant to at least one drug.

Mr. Speaker, the R&D pipeline for antibiotics is drying up. Major pharmaceutical companies simply are not investing in the development of new antibiotics because it's not as profitable as drugs that treat chronic conditions. This is an important provision that I believe will help reverse that trend and lead to new breakthroughs and help protect the public health.

Mr. Speaker, in addition to these two provisions, the bill before us contains several other technical changes that would improve the Medicare and Medicaid programs and generate savings.

I urge my colleagues on both sides of the aisle to support this legislation.

I reserve the balance of my time.

Mr. SULLIVAN. Mr. Speaker, I rise in support of S. 3560. The bill is designed to make technical corrections to policies we enacted in this and previous Congresses.

Specifically, this bill, at its core, corrects a technical error in the funding level for the extension of the QI-1 program that was passed earlier this year as part of the Medicare Improvements for Patients and Providers Act of 2008. The QI-1 program provides for the government's payment of Medicare part B premiums for certain low-income beneficiaries through the State Medicaid program.

In addition, this bill provides an important correction in FDA policy regarding the development of antibiotics. This provision would have been in the Food and Drug Administration Amendments Act that we passed last year; however, it was dropped at the last minute because of PAYGO reasons.

Finally, this bill provides the Secretary with additional authority to

perform education and outreach activities as part of the Medicaid Integrity Program established by the Deficit Reduction Act of 2005.

This bill is fully paid for, with some money left over to spare. The offset for this bill is the use of the State Public Assistance Reporting Information System. This system provides States with a tool to improve program integrity and go after fraud and abuse in the administration of public and medical assistance programs. This system does this by matching program enrollment data, such as Medicaid enrollment data, with data from other States which determine possible duplicate payments.

Mr. Speaker, I urge Members to support this legislation. However, I do want to remind Members that the need for a technical bill might not have arisen if the majority would have involved the minority in the crafting of the Medicare bill passed in July. The majority should have provided the minority time to review the legislation and offer a motion to recommit.

I support this legislation, but I hope moving forward the majority will include the minority when writing major legislation.

I yield as much time as the gentleman may consume to my friend from Michigan, DAVE CAMP.

Mr. CAMP of Michigan. Mr. Speaker, I thank the gentleman for yielding, and I'm also pleased to rise in support of this legislation, which will make important changes to the Qualified Individual program.

This program helps low-income Medicare beneficiaries pay for their Medicare premiums. While the QI program was extended under the Medicare Improvement for Patients and Providers Act enacted in July, some States were still facing shortfalls.

The bill we are debating today provides \$45 million to ensure States like Alabama and South Carolina have sufficient funds to maintain Medicare enrollment for their low-income seniors. Importantly, this bill is fully paid for by requiring State Medicaid programs to electronically submit eligibility determinations to the Public Assistance Reporting Information System.

Mr. Speaker, it is critical to the health of low-income seniors that we enact this legislation promptly, and I urge the House to support this bill.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from California, the chairman of the Ways and Means Health Subcommittee, Mr. STARK.

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

Mr. STARK. Mr. Speaker, my remarks shall be brief, because the distinguished ranking member of the Subcommittee on Health on the Committee on Ways and Means was participating and is so adequately up on this bill that he just said it all. I would associate myself with the remarks of the

distinguished gentleman from Michigan.

I rise in support of the QI Program Supplemental Funding Act, S. 3560.

At nearly \$100 a month, the Part B premium can be a real hardship for seniors living on low incomes.

This bill is necessary to ensure that low-income Medicare beneficiaries with annual incomes between \$12,000–\$14,000 are able to continue receiving financial assistance for the cost of their Medicare premiums.

I support extending this vital program. If this bill doesn't pass, States will drop poor seniors from the program.

My only complaint is that we should be doing more than this today. We have technical corrections from the Medicare legislation we passed earlier this year which should be before us as part of this legislation. Unfortunately, the Senate failed to reach agreement to incorporate those needed provisions in this bill.

There is much we need to do to maintain our commitment to Medicare and Medicaid. This bill is a tiny part of that work. I look forward to continuing to work with my colleagues on both sides of the aisle—and on both sides of the Capitol—to do much more.

Mr. SULLIVAN. Mr. Speaker, I yield to the gentleman from Virginia, Congressman WOLF, as much time as he may consume.

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

Mr. WOLF. I was watching this meeting and resolution in my office today, and I support it. I think it's a good issue, but I want to say to the gentleman from New Jersey, I don't understand why you've boxed up for months and years the bill that Congressman CHRIS SMITH has that deals with Lyme disease.

I was at a national Lyme disease conference this week. Lyme disease is spreading through our Nation. Lyme disease is spreading through my congressional district. Lyme disease is spreading through New Jersey, spreading through the gentleman's district, spreading through Mr. SMITH's district, and if I could get the gentleman's attention, rather than whispering back and forth, I would like to know, if we are going to do resolutions like this and take them out of the committee, why Mr. SMITH's bill, which has been pending in your committee for a long time, cannot be considered?

If you watched the movie the other day, the number of people that have been impacted by Lyme disease is very serious. This is spreading. It's in Pennsylvania, I would tell the person who's chairing the House. It is spreading throughout the United States, and yet the bill is boxed up, locked up in your committee, and I want to know, because I've had enough of seeing this thing and seeing it go time after time after time, and you're keeping the bill from coming out.

So if I could yield to the gentleman to tell me, what do you plan on doing about Lyme disease? Why won't you get that bill out? What is the status of

it? And what would we tell somebody who happens to have Lyme disease today to know that the bill is pending in the committee?

I yield to the gentleman.

Mr. PALLONE. Well, as I've discussed with the gentleman, because we have actually talked about this on several occasions, I believe we are now doing what we call consent bills, in other words, bills that have the consent, meaning are basically agreed to not only by the Democrats and Republicans, but also by the members of the subcommittee and the Members of the House in general, because as you know, you have to have a two-thirds vote to pass these bills or do them by unanimous consent.

We do not have anything near consensus on that legislation. It would have to go through regular order, have a hearing, go through subcommittee. The problem is that many, probably the majority, but I won't venture to say whether it's majority or minority, but many people do not agree with the protocol, if you will, that is suggested, if not mandated, by that legislation.

In other words, right now, the majority of the doctors treat Lyme disease, you know, in a certain fashion. Those who advocate for that legislation suggest a different protocol, and frankly, I have tried very hard as chairman of the Health Subcommittee not to mandate or make decisions for physicians as to what kind of protocols they use. In this case, the protocol is very different from the overwhelming majority of the doctors, and so it's a very controversial issue that needs to have a lot of debate.

So there's absolutely no way that we could do something like that on a consent calendar because many of the Members simply don't support it.

Mr. WOLF. Reclaiming my time, why hasn't the gentleman had hearings on it?

Mr. PALLONE. Well, we could certainly have hearings on it, and as I discussed with the gentleman, I would like to have hearings not only on that bill but on the issue of Lyme disease, research and treatment, and we will certainly do that in the next session. But we're obviously not doing this today in the context of a consent calendar.

Mr. WOLF. Reclaiming my time, I will take you at your word that you're going to have hearings, is that accurate, early in the year?

Mr. PALLONE. What I said is I would like to have hearings on the issue related to Lyme. We can certainly take up the issues that are raised in that legislation in the context of that, but as I would say to the gentleman again, the protocol in that legislation is very controversial. It's certainly one of the many things that we would have to consider in the context of research and treatment of Lyme disease.

Mr. WOLF. Reclaiming my time, we're not going to let this issue go away, I want to tell the gentleman from New Jersey, even if I have to

come up into New Jersey and go throughout to say that this bill is being boxed up.

Just so Members know, instances of Lyme disease are rapidly rising in Virginia, not only in my congressional district but across the country. According to the Centers for Disease Control and Prevention, from 1993 to 2007, reported cases of Lyme in Virginia have risen 990 percent, and this committee has done nothing. In the same time frame, reported cases are up 235 percent nationwide.

Lyme disease is frightening, keeps the Boy Scouts and Girl Scouts from camping during summer months or children playing in the backyard or joggers on bike paths through tree-lined neighborhoods, sharing the outdoors with a minute insect that can bring monumental health problems.

Congress needs to get serious. I was watching this and I think you have boxed it up. You know, when the gentleman was speaking—if you could look at me, I would just appreciate it. I want to tell the gentleman that we're going to hold you to this with regard to hearings. I will come and testify, but if this issue is boxed up next year, we're going to deal with it in many ways.

□ 1330

I would ask unanimous consent—if you want to say something, I'll wait.

Mr. PALLONE. Well, I would just say this: You know, it does bother me because the gentleman is sort of suggesting that you and I haven't had conversations about this. We've actually had many conversations about this. I've told you the same thing I've just said here on the floor. And I really don't understand why the gentleman is giving the impression that somehow we haven't discussed this because we have.

Mr. WOLF. Reclaiming my time, I never said—we've discussed it twice. What I'm saying is that you've boxed the bill up, you've boxed CHRIS SMITH's bill up. You've held no hearings. And there are a lot of people around the country that are suffering with Lyme disease. And you appear to be the rail block. And so what we're asking for is hearings, and give us an opportunity for all people of all sides to be heard.

Mr. PALLONE. Would the gentleman yield?

Mr. WOLF. I would yield.

Mr. PALLONE. First of all, I resent the fact that the gentleman is suggesting that we "boxed this up." I would point out to the gentleman that the problem of Lyme disease has been around for many years. And the gentleman and his committee, Appropriations Committee, were in the majority for, what, at least 12 years before the last 2 years that the Democrats have been in the majority? Certainly, the gentleman had plenty of opportunity, and still does, to do something about this himself.

Mr. WOLF. Reclaiming my time, I was going to offer the Chris Smith amendment to the appropriations bill.

The Appropriations Committee hasn't met and had any hearings for months. Your side has prohibited any amendments from being offered. But I will tell the gentleman, next year, if you don't move this bill, I am going to offer it to the Labor-H bill next year and we will have to deal with it on the floor.

I believe we have a responsibility to address an issue that is wreaking havoc in my district and across the country. That's the rapid rise in Lyme disease and there is a bill pending in the Energy and Commerce Health Subcommittee that could go a long way towards helping raise awareness about the threat of Lyme.

Just this week I went to a briefing sponsored by the National Capital Lyme and Tick-Borne Disease Association. People are suffering from Bell's palsy, meningitis and other manifestations from Lyme disease.

There are people in my district whose entire nuclear family suffers from chronic Lyme: Young men and women who have had to take medical leave from their college studies to battle severe joint pain and bleeding ulcers, once healthy people unable to dress themselves or tie their shoes; and folks hundreds of thousands of dollars in debt just trying to get some quality of life back for their loved ones.

Americans need to learn about Lyme and press their Federal legislator to act. It is unacceptable—an outrage—for Congress to ignore this issue.

This past August I held a Lyme disease awareness forum in my district in Loudoun County, Virginia, to help my constituents learn how to prevent Lyme disease from touching their families. Three medical doctors, including two county health departments, volunteered their time to share their expertise in Lyme-related issues.

Lyme disease is an illness caused by bacteria that are transmitted to people by the bite of an infected black-legged tick, also known as the deer tick, which is comparable in size to the tip of a ball point pen. With all of the natural beauty and outdoor activities in many of the congressional districts we represent, it's important we work to educate our constituents about this debilitating disease.

Speaking as a father of five and grandfather of 13, I worry about deer, mice, and even family pets transmitting ticks and transmitting Lyme.

Incidents of Lyme disease are rising rapidly in Virginia and across the country. According to the Centers for disease Control and Prevention, from 1993 to 2007 reported cases of Lyme in Virginia have risen 909 percent. In that same time frame, reported cases are up 235 percent nationwide.

Lyme disease is frightening. Picture Boy Scouts and Girl Scouts camping during the summer months or children playing in the backyard, or joggers on bike paths through tree-lined neighborhoods—sharing the outdoors with a minute insect that can bring monumental health problems.

This Congress needs to get serious about stepping up to the plate, and making sure people in high risk areas are aware of this threat. H.R. 741—The Lyme and Tick-Borne disease Prevention, Education, and Research Act—legislation introduced by CHRIS SMITH with a host of original cosponsors from New York, Connecticut, Arizona, Illinois, Rhode Island, Washington, among others, now has collected well over 100 bipartisan cosponsors.

The bill, which would expand Federal efforts with respect to prevention, education, and research activities, will go a long way toward getting the word out about Lyme disease and the precautions people can take to ensure that they never have to suffer the consequences of chronic Lyme.

"An ounce of prevention is worth a pound of cure" could not be a more appropriate adage for Lyme disease. Failure to recognize Lyme disease early in its course can result in the development of difficult to treat infections in the brain, eyes, joints, heart, and elsewhere in the body.

As public servants, we have given our word to do everything we can to protect the public interest. We are sorely lacking in Federal efforts to increase awareness and education about Lyme disease. Every year since 1998, legislation similar to H.R. 741 has been introduced in the House, and we have failed to act.

I urge every member to educate themselves on the Lyme statistics in their home state and take a close look at H.R. 741.

For those Members who sit on the Energy and Commerce Subcommittee on Health, I urge you to step forward and act to see that this bill is reported out of committee before the House completes its legislative business for the 110th Congress.

For the House leadership, I urge that this bill be placed on the calendar now for action. If we can spend time loading up the suspension calendar and voting on commemorative anniversaries and naming post offices, we surely can find time to address legislation that can make a difference in the lives of Americans.

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

I would just point out that on this and so many other issues it is amazing to me that the gentleman, who was in the majority for so many years and had so many opportunities to raise this and other issues, is somehow now suggesting that the Democrats are boxing it up. You know, Lyme has been around for a long time. The people concerned about this issue have been trying to address it for a long time. The bottom line, as the gentleman knows, it's a very controversial issue. We will certainly raise it, but he had ample opportunity, the many years that he was in the majority, to raise it and it just didn't happen.

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

Mr. SULLIVAN. Mr. Speaker, may I inquire as to how much time is remaining?

The SPEAKER pro tempore. The gentleman from Oklahoma has 8½ minutes remaining.

Mr. SULLIVAN. Mr. Speaker, I yield as much time as he might consume to Mr. WOLF.

Mr. WOLF. This is a growing issue. It is becoming a more important issue and a new issue. If you look at the statistics, it is growing around the Nation, it is now becoming an epidemic. And so, when I now see an epidemic taking place in my congressional district, in your congressional district, through New Jersey, through Connecticut—if you talk to Senator DODD, he will tell you—through Massachusetts, all up and down the east coast, it is time to do something. And so I think it is time to deal with it.

And I see the gentleman from New Jersey here. You have blocked this bill for a long period of time. And I will tell you, I will not permit you to block it. And next year, I will offer amendment after amendment after amendment and do whatever I can to make sure that people who are impacted by this, to make sure that people who do not even know what may very well be threatening them will not be threatened.

I yield to the gentleman from New Jersey to also make some comments about this.

Mr. SMITH of New Jersey. I thank my friend for yielding.

Mr. Speaker, first of all, I want to thank Mr. WOLF for raising this. I didn't know he was going to be doing it; I just saw him on the television.

Mr. WOLF. I didn't know I was going to be doing it until I saw the gentleman, Mr. PALLONE, standing up and taking this up on suspension.

Mr. SMITH of New Jersey. So I appreciate the gentleman yielding.

Let me just say, to clarify the record, this legislation, which would seek to lay bare the science about Lyme disease, the fact that I believe we do have an epidemic, the fact that Lyme often go misdiagnosed, underdiagnosed. It is called "the great pretender" because so many people have it and don't know it. It often masquerades as other kinds of anomalies manifesting in a person's body. And it is not until it gets to a chronic state—very often causing severe disability, including neurological damage—that people finally realize that they have Lyme disease.

There has been, unfortunately, a significant, I believe, cover up of the fact that chronic Lyme exists. The gentleman knows, we have asked him repeatedly, the gentleman from New Jersey, my good friend, Mr. PALLONE, this legislation has been pending in his subcommittee. He told Pat Smith—no relation to me—who runs a Lyme disease association, that this would get a hearing and would be marked up. It has not been marked up. And meanwhile, this epidemic is growing—it is exploding.

Now, let me just say for the enlightenment of my colleagues; the Infectious Disease Society of America,

which creates—and often does a very laudable job—the definitions, the parameters of what constitutes a certain disease, has looked at Lyme and said that chronic Lyme does not exist. Many of us have raised serious concerns about that because of what we believe to be conflicts of interest on the part of the panel members that made up the Lyme panel.

I would note parenthetically that CHRIS DODD is the prime sponsor of the comparison legislation that I've introduced on the House side. We have worked cooperatively on the legislation, so we have a companion bill on the Senate side. The legislation has over 110—I think it's 112—cosponsors, totally bipartisan, Democrats and Republicans alike rallying around this legislation.

The problem with the Infectious Disease Society of America is that these conflicts of interest, we believe, resulted in the conclusion that chronic Lyme doesn't exist. We don't know absolutely if that's the truth, but Attorney General Richard Blumenthal from Connecticut finally took a look at this and came back with a scathing insightful report that there were conflicts of interest. The red flag should go up everywhere.

What does my legislation do? As Mr. PALLONE knows, the legislation does not prescribe a protocol, as he has suggested. It simply calls for an advisory committee that would take a good, long look at Lyme disease and determine what is fact and fiction, and finally, for the sake of all of those who are suffering immensely from this disease and their families, say what we need to be doing to mitigate and hopefully stop the spread of Lyme, whether it be long-term and very heavy antibiotic treatment—which I believe probably is the case based on clinical practitioners who have suggested that to be the case—but we want an honest look.

As Mr. PALLONE knows, we did not get an honest look from the Infectious Disease Society of America. And I find that appalling. Conflict of interest with insurance companies has no place in modern medicine. And regrettably, and it has been—again, the full weight of the Attorney General's report clearly suggests, Richard Blumenthal of Connecticut, that there were significant conflicts of interest on the part of the panel members.

Our legislation says let's go where the science takes us. If the science says chronic Lyme exists, then all those patients and the insurance companies which need to be providing the coverage, to get the medicines and the like, like antibiotics—because what has happened, as my friend knows, because of this exclusion of chronic Lyme due to a problem in definition, the insurance companies say we don't have to pay. So when a patient presents with a bill of \$100,000 or some excessive amount of money, the insurance companies say, not us, tough luck, we're not going to pay for it. And they go

right back to what I believe to be a false definition that precludes chronic Lyme as a condition.

Now, you might think that chronic Lyme doesn't exist, I say to my friend, the chairman, but let's go where the science takes us. We need this advisory committee and we need it now. All points of view, as our legislation clearly suggests, has to be a part of this group. We want a robust debate, not something that is engineered by insurance companies.

Finally, the legislation would authorize \$100 million over 5 years, \$20 million each year. Frankly, if that drops off due to opposition to new authorization, and is only an authorization, I would like to see it go forward nevertheless, know this however, we're not spending enough on Lyme.

And Lyme is, as Mr. WOLF said so aptly, growing exponentially. CDC admits we are missing most of the cases. As many as 90 percent of the cases go unreported. Our state, Mr. PALLONE, as you know, is number three in prevalence according to CDC numbers, and even that is probably very much understated in terms of the actual prevalence of Lyme disease.

So I would make the appeal again, as I have made to my friend from New Jersey, as I have made to Mr. DINGELL, as I have made to Mr. BARTON and everyone else, this legislation ought to be on this floor and it ought to be on the floor today. It is truly bipartisan. There ought to be a consensus to go where the science takes us. And again, an advisory committee, a Blue Ribbon panel that would be configured under this legislation would finally end, hopefully, this contentious debate and tell us what it is and what it is not.

I have known dozens of people who have had chronic Lyme. Now, you might say it doesn't exist, the Infectious Disease Society says it doesn't exist. These victims suffer from the spirochete, and have suffered neurological damage, severe joint damage, and many, many other problems.

There is a new book called "Cure Unknown" that I would recommend to the House. I read it in one sitting because it is so incisive in finally breaking through the fog on this disease. People are walking around with Lyme and they don't even know it.

We need to bring the forces to bear of the U.S. Government that an advisory committee of this kind would do a Blue Ribbon panel, a 9/11-type panel of scientists, of the best people we can put together to say, put aside the egregiously flawed Infectious Diseases Society of America's finding, which Blumenthal said was riddled with conflict of interest—and I urge Members to read Blumenthal's opinion, I will put it in the RECORD so Members can read it—his findings were, "atrocious, conflict of interest everywhere."

This legislation ought to be on the floor and it ought to be on the floor today.

OFFICE OF THE ATTORNEY GENERAL,

Hartford, Connecticut, May 1, 2008.

ATTORNEY GENERAL'S INVESTIGATION REVEALS FLAWED LYME DISEASE GUIDELINE PROCESS, IDSA AGREES TO REASSESS GUIDELINES, INSTALL INDEPENDENT ARBITER

Attorney General Richard Blumenthal today announced that his antitrust investigation has uncovered serious flaws in the Infectious Diseases Society of America's (IDSA) process for writing its 2006 Lyme disease guidelines and the IDSA has agreed to reassess them with the assistance of an outside arbiter.

The IDSA guidelines have sweeping and significant impacts on Lyme disease medical care. They are commonly applied by insurance companies in restricting coverage for long-term antibiotic treatment or other medical care and also strongly influence physician treatment decisions.

Insurance companies have denied coverage for long-term antibiotic treatment relying on these guidelines as justification. The guidelines are also widely cited for conclusions that chronic Lyme disease is non-existent.

"This agreement vindicates my investigation—finding undisclosed financial interests and forcing a reassessment of IDSA guidelines," Blumenthal said. "My office uncovered undisclosed financial interests held by several of the most powerful IDSA panelists. The IDSA's guideline panel improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science."

"The IDSA's Lyme guideline process lacked important procedural safeguards requiring complete reevaluation of the 2006 Lyme disease guidelines—in effect a comprehensive reassessment through a new panel. The new panel will accept and analyze all evidence, including divergent opinion. An independent neutral ombudsman—expert in medical ethics and conflicts of interest, selected by both the IDSA and my office—will assess the new panel for conflicts of interests and ensure its integrity."

Blumenthal's findings include the following: The IDSA failed to conduct a conflicts of interest review for any of the panelists prior to their appointment to the 2006 Lyme disease guideline panel;

Subsequent disclosures demonstrate that several of the 2006 Lyme disease panelists had conflicts of interest;

The IDSA failed to follow its own procedures for appointing the 2006 panel chairman and members, enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by or formal approval of the IDSA's oversight committee;

The IDSA's 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a panelist from the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve "consensus";

The IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006 guidelines panel by informing them that the panel was fully staffed, even though it was later expanded;

The IDSA portrayed another medical association's Lyme disease guidelines as corroborating its own when it knew that the two panels shared several authors, including the chairmen of both groups, and were working on guidelines at the same time. In allowing its panelists to serve on both groups at the same time, IDSA violated its own conflicts of interest policy.

IDSA has reached an agreement with Blumenthal's office calling for creation of a review panel to thoroughly scrutinize the 2006 Lyme disease guidelines and update or revise them if necessary. The panel—composed of individuals without conflicts of interest—will comprehensively review medical and scientific evidence and hold a scientific hearing to provide a forum for additional evidence. It will then determine whether each recommendation in 2006 Lyme disease guidelines is justified by the evidence or needs revision or updating.

Blumenthal added, "The IDSA's 2006 Lyme disease guideline panel undercut its credibility by allowing individuals with financial interests—in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies—to exclude divergent medical evidence and opinion. In today's healthcare system, clinical practice guidelines have tremendous influence on the marketing of medical services and products, insurance reimbursements and treatment decisions. As a result, medical societies that publish such guidelines have a legal and moral duty to use exacting safeguards and scientific standards.

"Our investigation was always about the IDSA's guidelines process—not the science. IDSA should be recognized for its cooperation and agreement to address the serious concerns raised by my office. Our agreement with IDSA ensures that a new, conflicts-free panel will collect and review all pertinent information, reassess each recommendation and make necessary changes.

"This Action Plan—incorporating a conflicts screen by an independent neutral expert and a public hearing to receive additional evidence—can serve as a model for all medical organizations and societies that publish medical guidelines. This review should strengthen the public's confidence in such critical standards."

#### THE GUIDELINE REVIEW PROCESS

Under its agreement with the Attorney General's Office, the IDSA will create a review panel of eight to 12 members, none of who served on the 2006 IDSA guideline panel. The IDSA must conduct an open application process and consider all applicants.

The agreement calls for the ombudsman selected by Blumenthal's office and the IDSA to ensure that the review panel and its chairperson are free of conflicts of interest.

Blumenthal and IDSA agreed to appoint Dr. Howard A. Brody as the ombudsman. Dr. Brody is a recognized expert and author on medical ethics and conflicts of interest and the director of the Institute for Medical Humanities at the University of Texas Medical Branch. Brody authored the book, "Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry."

To assure that the review panel obtains divergent information, the panel will conduct an open scientific hearing at which it will hear scientific and medical presentations from interested parties. The agreement requires the hearing to be broadcast live to the public on the Internet via the IDSA's website. The Attorney General's Office, Dr. Brody and the review panel will together finalize the list of presenters at the hearing.

Once it has collected information from its review and open hearing, the panel will assess the information and determine whether the data and evidence supports each of the recommendations in the 2006 Lyme disease guidelines.

The panel will then vote on each recommendation in the IDSA's 2006 Lyme disease guidelines on whether it is supported by the scientific evidence. At least 75 percent of panel members must vote to sustain each recommendation or it will be revised.

Once the panel has acted on each recommendation, it will have three options: make no changes, modify the guidelines in part or replace them entirely.

The panel's final report will be published on the IDSA's website.

#### ADDITIONAL FINDINGS OF BLUMENTHAL'S INVESTIGATION

IDSA convened panels in 2000 and 2006 to research and publish guidelines for the diagnosis and treatment of Lyme disease. Blumenthal's office found that the IDSA disregarded a 2000 panel member who argued that chronic and persistent Lyme disease exists. The 2000 panel pressured the panelist to conform to the group consensus and removed him as an author when he refused.

IDSA sought to portray a second set of Lyme disease guidelines issued by the American Academy of Neurology (AAN) as independently corroborating its findings. In fact, IDSA knew that the two panels shared key members, including the respective panel chairmen and were working on both sets of guidelines at the same time—a violation of IDSA's conflicts of interest policy.

The resulting IDSA and AAN guidelines not only reached the same conclusions regarding the non-existence of chronic Lyme disease, their reasoning at times used strikingly similar language. Both entities, for example, dubbed symptoms persisting after treatment "Post-Lyme Syndrome" and defined it the same way.

When IDSA learned of the improper links between its panel and the AAN's panel, instead of enforcing its conflict of interest policy, it aggressively sought the AAN's endorsement to "strengthen" its guidelines' impact. The AAN panel—particularly members who also served on the IDSA panel—worked equally hard to win AAN's backing of IDSA's conclusions.

The two entities sought to portray each other's guidelines as separate and independent when the facts call into question that contention.

The IDSA subsequently cited AAN's supposed independent corroboration of its findings as part of its attempts to defeat federal legislation to create a Lyme disease advisory committee and state legislation supporting antibiotic therapy for chronic Lyme disease.

In a step that the British Medical Journal deemed "unusual," the IDSA included in its Lyme guidelines a statement calling them "voluntary" with "the ultimate determination of their application to be made by the physician in light of each patient's individual circumstances." In fact, United Healthcare, Health Net, Blue Cross of California, Kaiser Foundation Health Plan and other insurers have used the guidelines as justification to deny reimbursement for long-term antibiotic treatment.

Blumenthal thanked members of his office who worked on the investigation—Assistant Attorney General Thomas Ryan, former Assistant Attorney General Steven Rutstein and Paralegal Lorraine Measer under the direction of Assistant Attorney General Michael Cole, Chief of the Attorney General's Antitrust Department.

CONGRESS OF THE UNITED STATES,

Washington, DC, May 18, 2007.

Hon. FRANK PALLONE, Jr.,

Chairman, Subcommittee on Health, House Committee on Energy and Commerce, Washington, DC.

DEAR CHAIRMAN PALLONE: As co-chairs of the congressional Lyme Disease Caucus, we are writing to respectfully request that you mark-up and report H.R. 741 or find a suitable legislative vehicle to attach significant provisions of this desperately needed legislation.

H.R. 741, the "Lyme and Tick-borne Disease Prevention, Education, and Research

Act of 2007," would work toward goals for the prevention, accurate diagnosis, and effective treatment of Lyme disease and would authorize an increase in total research and education funding of \$20 million per year over 5 years. The bill contains numerous measures to help ensure that resources are expended effectively to provide the most benefit to people with Lyme and other tick-borne diseases.

Introduced in January, this legislation currently has 77 bipartisan co-sponsors. It is supported by more than 60 Lyme disease organizations across the country. This legislation holds the promise to significantly improve the lives of the large numbers of Americans living with Lyme, as well as other tick-borne diseases, and their families and friends.

Lyme is the most prevalent vector-borne disease in the United States today. More than 220,000 Americans develop Lyme each year. According to the Centers for Disease Control & Prevention (CDC), only 10 percent of cases that meet its surveillance criteria are reported. Cases that fall outside the surveillance criteria are not even considered anywhere statistically.

If not diagnosed and treated early, Lyme disease can lead to chronic illness and can affect every system in the body, including the central nervous system and cardiac systems. Later symptoms of Lyme disease include arthritis, neurological problems, such as facial paralysis, encephalopathy, memory problems, weakness of the extremities, seizures, heart block and inflammation of the heart muscle, and even blindness.

In recent years, Lyme disease has continued an upward trend in endemic areas and also has expanded into more areas. Reported Lyme cases increase, by 100 percent from 1992 to 2004 according to CDC. Currently, all states except Montana have reported cases of Lyme disease. It even has been reported that Montana residents have gone outside of the State and tested positive for Lyme). It is far more common than all other insect-borne diseases. Now other diseases are being carried by the same ticks: babesiosis, naplasmosis, encephalitis, perhaps bartonellosis.

While the emergence of Lyme disease in the Northeastern and mid-Atlantic states has been linked to reforestation, climate change also is an influencing factor. According to a November 2005 report by the Center for Health and the Global Environment at the Harvard Medical School, "Climate Change Futures: Health Ecological and Economic Dimensions," Lyme disease is spreading in North America and Europe as winters warm. . . . In areas where Lyme disease is already present, warming temperatures may increase the density of ticks by increasing off-host survival.

Over the past decade and with the increase in Lyme cases, problems with diagnosis and treatment of Lyme disease have become much more visible—affecting larger numbers of people over longer periods of time. We have become increasingly concerned with reports of patients who go long periods of time before getting a definitive diagnosis due to the lack of a gold standard diagnostic test and who received delayed or inappropriate treatment because of the lack of treating physicians nationwide and lack of physician education. Many patients lose their jobs and must apply for disability.

In consideration of these conditions the Federal investment in Lyme is surprisingly small—\$5.4 million at CDC and \$24 million at NIH in FY 2006, actual reductions at both agencies since 2004. While funding levels are a means to an end, the ultimate goal is to put an end to patients having their illnesses and disabilities greatly exacerbated by the lack of accurate diagnostics and effective



treatments. HR 741 addresses this goal by directing HHS to work toward development of a sensitive and accurate diagnostic test: improved surveillance and prevention, and clinical outcomes research to determine the long-term course of illness and the effectiveness of treatments. In addition, the bill would establish a Tick-Borne Disease Advisory Committee to ensure communication and coordination among federal agencies, medical professionals, and patients/patient advocates. The Lyme community has been seeking this voice for a decade.

As Chairman of the Energy and Commerce Committee, we know that you share our commitment to significantly improve the health outlook for all citizens of this country, including the hundreds of thousands of Americans who have experienced or will experience the too common occurrence of being bitten by Ixodes scapularis, the deer tick or black legged tick, and contracting Lyme disease. *Amblyomma americanum*, the lone star tick, is rapidly spreading throughout the country from its former more southern habitat, and states in the northeast are beginning to feel its impact as it spreads. STARI, a Lyme like illness with the same symptoms as Lyme disease. It also carries Ehrlichiosis or tularemia. Scientists are saying that this lone star is aggressive and will pursue people from 30 feet away, not like the deer tick which waits for its prey sitting on vegetation.

To ensure that these necessary goats are not lost, we respectfully request that you schedule for a mark-up the Lyme and tick-borne Disease Prevention, Education, and Research Act of 2007. If you have any questions on this matter, please do not hesitate to contact us.

Sincerely,

CHRISTOPHER H. SMITH,

*Member of Congress.*

TIM HOLDEN,

*Member of Congress.*

The SPEAKER pro tempore. All time from the gentleman from Oklahoma has expired.

The gentleman from New Jersey has 16 minutes remaining.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I might consume.

First of all, I want to say to the gentleman from New Jersey, he has made a lot of statements about my views on this subject which are simply not true, and I do not appreciate them.

Mr. SMITH of New Jersey. Will the gentleman yield?

Mr. PALLONE. Mr. Speaker, I have no intention of yielding to the gentleman because of the disrespect that he has shown.

Now, secondly, let me also say this: I do appreciate the fact that the gentleman from Virginia (Mr. WOLF) has, on several occasions, come up to me in the last few months and talked to me about this legislation. And we've had very reasoned conversations about the legislation. But I will also point out that the gentleman from New Jersey has not. The gentleman from New Jersey has not spoken to me at all about this legislation, and certainly not, in my recollection, in the last year. So if he felt it was so important, the way the gentleman from Virginia did, and has, he certainly had many opportunities to come up to me and talk to me about it. He has not. And I see the gentleman from New Jersey all the time—

on the floor, at home, on various occasions. He has not spoken to me.

So I want to thank the gentleman from Virginia for at least saying that he has taken the time, had some reasoned discussions about it. That is not true of my colleague from New Jersey, which is why I deeply resent the fact that he's on the floor here today talking about it because it is the first time I recollect him ever talking to me about it.

Now, let me say a few other things. First of all, as far as the science is concerned, the science is in the Infectious Diseases Society and the CDC, not with the Attorney General and some political grandstanding that he's doing in Connecticut, nor with my colleague from New Jersey who is grandstanding here today.

I am very concerned about Lyme disease. I have been working with the CDC to address the issue. We are awaiting answers from the agency on how best to address this. I have, in fact, talked to many of my constituents about this, even though my own colleague hasn't talked to me about it from New Jersey.

And I also would like to say this: As far as the Infectious Diseases Association, they basically are the majority opinion. Many doctors, including my neighbors who are physicians in my hometown, very much agree with the Infectious Diseases Society and don't think that this should be treated with these antibiotics for a long period of time because they're concerned about the impact on people and whether they would be seriously injured or even die from the antibiotics.

There is a lot of controversy that involves this issue. It is very involved and it is very controversial. It shouldn't be considered today on a consent calendar. And that was the only point I was trying to make for my colleague from Virginia, that we need to have hearings. And we will have hearings on the issue in general, and we can include this bill as part of that in the next session. But to bring this up today on the consent calendar when they know very well that there is no agreement on this and we couldn't possibly get a UC or have this on the suspension calendar, it's really very upsetting, and particularly coming from my colleague from New Jersey, who has never talked to me about this at all.

Mr. DINGELL. Mr. Speaker, I support S. 3560, the "QI Supplemental Funding Act of 2008". The Qualified Individuals Program (QI) is a program within Medicaid that helps low-income seniors and individuals with disabilities pay their Medicare Part B premium. The Medicare Improvements for Patients and Providers Act of 2008 extended the funding for the QI program through December 2009.

Projections, however, regarding the amount of funding necessary to ensure continuation of this program through next year were incorrect. Without Congressional action to add an additional \$45 million to the QI program, seniors and individuals with disabilities who have an income as low as \$12,500 will be in jeopardy of losing this needed assistance.

The cost of this provision is fully offset with a provision that requires States to improve their Medicaid eligibility determinations by using the Public Assistance Reporting Information System (PARIS) interstate match. PARIS helps States share information regarding public assistance programs, such as Temporary Assistance for Needy Families (TANF), Food Stamps, and Medicaid, to identify individuals or families who may be receiving benefit payments in more than one State.

Similarly, S. 3560 includes a clarification to ensure that the Medicaid Integrity Program created in the Deficit Reduction Act of 2005, to operate as intended. The Medicaid Integrity Program performs audits and educates providers, Federal and State employees, and others on payment integrity and quality of care initiatives. The provision would allow for Federal reimbursement of state employees for these program integrity initiatives.

Finally, this package includes a provision which states that any antibiotic that was the subject of an application submitted to the Food and Drug Administration, but was not approved, can get the three-year and/or five-year "Hatch/Waxman exclusivity" or a patent term extension.

I urge all my colleagues in the House to vote in favor of S. 3560.

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

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the Senate bill, S. 3560.

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

A motion to reconsider was laid on the table.

□ 1345

#### PAUL D. WELLSTONE MUSCULAR DYSTROPHY COMMUNITY ASSISTANCE, RESEARCH, AND EDUCATION AMENDMENTS OF 2008

Mr. PALLONE. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the bill (H.R. 5265) to amend the Public Health Service Act to provide for research with respect to various forms of muscular dystrophy, including Becker, congenital, distal, Duchenne, Emery-Dreifuss facioscapulohumeral, limb-girdle, myotonic, and oculopharyngeal, muscular dystrophies, with a Senate amendment thereto, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

MOTION OFFERED BY MR. PALLONE

Mr. PALLONE. Mr. Speaker, I have a motion at the desk.

The Clerk read as follows:

Mr. PALLONE of New Jersey moves that the House concur in the Senate amendment to H.R. 5265.

The text of the Senate amendment is as follows:

Senate amendment:

Strike all after the enacting clause and insert the following: