Mr. BLIRAKIS. Mr. Speaker, I rise today in support of H.R. 4013, the Rare Diseases Act of 2002. This bill, which was introduced by the gentleman from Illinois, Mr. SHIMKUS, would help improve research on rare diseases at the National Institutes of Health. I urge my colleagues to join me today in supporting this important legislation.

A rare or “orphan” disease affects fewer than 200,000 people in the United States. There are more than 6,000 rare disorders that, taken together, affect approximately 25 million Americans. One in every 10 individuals in this country has received a diagnosis of a rare disease.

H.R. 4013 will help focus research on rare diseases at NIH. The bill also specifically gives NIH the authority to support regional centers of excellence in rare disease research. This bill will help strengthen our national research infrastructure in this area and improve our ability to treat and hopefully cure numerous rare diseases.

The Energy and Commerce Committee approved H.R. 4013 in late June, and I again urge my colleagues to support this important bill.

Mr. SHIMKUS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. SHIMKUS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. BOOZMAN). The question is on the motion to postpone. There are no further requests for time, and I again urge my colleagues to support this important bill.

Mr. SHIMKUS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I rise today in support of this legislation. Mr. Speaker, this is really my first day ever managing a bill on the floor of the House. I have done a lot of other things from speaking to presiding but never actually managing a bill; and it is really appropriate that this legislation that we just took up, H.R. 4013, and this piece of legislation, H.R. 4014, I cannot think of a better bill to have a chance to manage. And so I thank my chairman and the subcommittee chairman for doing that.

Mr. Speaker, I also want to take this time to say that it is an honor to be managing with my friend, the gentleman from California (Mr. WAXMAN), because many times we are opponents on legislative matters. One of the great things about this institution is when we can work together from across the political divide and ideological divide to find issues that we become impassioned about and we join in forces that can help move legislation. So I extend my thanks to my friend from California (Mr. WAXMAN) and this will be a memorable day for me as I think back on my congressional career.

Mr. Speaker, I rise today in support of this legislation, H.R. 4014, the Rare Disease Orphan Product Development Act of 2002. This bill is sponsored by my good friend, the gentleman from Florida (Mr. FOLEY), who will join us in a minute, and the gentleman from California (Mr. WAXMAN), and will increase the authorization for grants given to researchers who are developing drugs, and treatments for rare diseases. With more money available to these researchers, we will be better able to find cures for the 6,000 rare diseases affecting nearly 25 million Americans. And when you know a family who has someone affected by rare diseases, it does not seem that rare because it is time consuming, it is costly, and for doing that really be passionate about making sure everybody has some help in trying to find cures and drugs to help them alleviate the onset of their disease.

Prior to the passage of the Orphan Drug Act in 1983, only a handful of drug and biologics had been developed to treat rare diseases. The reasons for this were simple. There was very little economic incentive for drug companies to spend the hundreds of millions of dollars it takes to develop a drug for a patient population too small for investment. That is why prior to 1983 only 38 drugs had been developed for rare diseases.
The Orphan Drug Act changes this by doing three things: offering greater exclusivity for drugs designed to treat diseases affecting fewer than 200,000 Americans, the establishing of a grant program for researchers performing clinical trials on orphan drugs, and providing a tax incentive for companies that make them.

The Orphan Drug Act has been a rousing success. Whereas fewer than 40 drugs have been developed in the past for rare diseases, in the past few decades more than 300 drugs have been developed and approved to treat these diseases. The bill before us today authorizes a grant program contained within the bill. Presently the government funds fewer than 100 researchers performing clinical trials into rare diseases, cures and therapies. While the demand is much higher, funding has been limited. This bill reauthorizes the grant program at 25 million in fiscal years 2003 through 2006, meaning even more money available by finding cures for these diseases.

Mr. Speaker, I rise in strong support of this bill and commend the gentleman from Florida (Mr. FOLEY) and the gentleman from California (Mr. WAXMAN) for their sponsorship of this legislation.

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

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

Mr. Speaker, I also rise in support of this bill, and I am honored to be a co-sponsor with the gentleman from Florida (Mr. FOLEY) and the gentleman from California (Mr. SHIMKUS) in this legislation.

This bill and the previous one are two bills that are furthering the cause of developing drugs for people with rare diseases. It is very important for the progress of research on treatments and to find cures for rare diseases. There are 6,000 rare diseases that affect approximately 25 million Americans. These diseases include cystic fibrosis, Lou Gehrig’s disease, muscular dystrophy, to underscore three of the well-known diseases that affect less than 200,000 people, and, therefore, are designated as rare.

The availability of safe and effective treatments for rare diseases has historically been limited due to the lack of incentive for pharmaceutical firms to commercialize such medications. To address this problem, Congress passed the Orphan Drug Act, which allows for market exclusivity for products developed for rare diseases, as well as special tax treatment for the companies that are willing to make that investment.

In addition, the Food and Drug Administration supports small clinical trials through orphan products search grants. These grants have led to the development of at least 23 drugs and four medical devices for rare diseases. The purpose of this legislation is to increase the national investment in the development of diagnostics and treatments for people with rare diseases.

H.R. 4014 is for the funding of the Orphan Product Research Grant Program, and increases the national investment in the development of diagnostics and treatment for patients with these rare diseases. It is a good piece of legislation. I am pleased and honored to be a co-sponsor of this bill and hope my colleagues will join us in supporting H.R. 4014.

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

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

Mr. Speaker, I rise in strong support of this bill and commend the gentleman from Florida (Mr. FOLEY), a major sponsor of the legislation.

Mr. FOLEY. Mr. Speaker, I congratulate the gentleman on his management of this important piece of legislation.

If I were Speaker of the House, I would probably declare that the only business on the House floor would be health care legislation because the bipartisanism displayed in this very important legislation is really indicative of the heart of this Chamber. Many people see us in vigorous debate over issues and why they cannot get along. Yet today you see the gentleman from Illinois (Mr. SHIMKUS) and the gentleman from California (Mr. WAXMAN) and myself all really focused on people who have been heard by us but have not been heard by society in general.

Today I rise in strong support of our mutually agreed-upon bill, H.R. 4014, the Rare Disease Orphan Product Development Act of 2002. This important piece of bipartisan legislation will encourage better treatment, diagnostic procedures, and cures for large numbers of rare diseases and disorders.

The gentleman from California (Mr. WAXMAN) mentioned the statistics, 25 million people suffering from more than 6,000 rare diseases. A rare disease, to underscore, is one that affects the population under 200,000 people, or about one in 11 Americans.

Mr. Speaker, I would like to mention just one of those Americans, a little girl fighting for her life. Her name is Madison, but her parents call her Maddy. She is a 5-year-old constituent of the gentleman from California, Mr. Bilirakis, one year after she was born. This horrible disease causes shortness of stature, mental retardation, speech and hearing impairments, heart disease, and worst of all a shortened life span.

As with most persons suffering from rare diseases, her situation is made worse because there may be only one or two doctors in the world working on a cure for her disease. Our bill would double the amount currently authorized for the Orphan Product Development Grant Program from $12 million to $25 million per year. This grant program is considered one of the most successful programs at the Food and Drug Administration. To date, 23 drugs and four medical devices have been developed as a direct result of this medical program, 23 drugs and four medical devices. This is an extraordinary achievement, given these products are generally far more financially attractive for the companies that make them.

Let me stop there and go just a bit off script because during the political season it is very, very easy to beat up the pharmaceutical industry to be the one that seems to be a target on both sides of the aisle. And yet today we are talking about companies that truly do God’s work here on Earth. They are working hard to develop the kind of resources and procedures, medications and things necessary to save lives. So while we can have our quarrel and disagreement with the industry over certain items, I do think it appropriate that on occasion we speak up for their great research. We are the envy of the world in development of pharmaceuticals, aids, and other things in this country. We are the envy of the world, and we should not lose sight that scientists are working collaboratively with some of these well-known brand-name manufacturers who are in fact shining some light and hopefully some hope for the people suffering.

Mr. Speaker, this medical minority cannot be ignored any longer. We cannot afford to keep paying 50 cents on the dollar when these patients are feeling 100 percent of the pain. It is time to raise the level of awareness of these diseases once and for all.

Mr. Speaker, I want to thank the gentleman from Illinois (Mr. SHIMKUS), the gentleman from Florida (Mr. BILIRAKIS), and the gentleman from California (Mr. WAXMAN), the ranking member, for their extraordinary efforts for bringing this issue to the national spotlight and for bringing these bills to the floor; I also want to commend my staff legislative counsel, Bradley Shieber, who is here today to bring these bills to my attention months ago. It is actually the fastest piece of legislation in my 7½-plus years in Congress that has come from a drafting, to a conclusion, to an introduction on the House floor, to hopefully a successful passage today.

Mr. Speaker, I would also like to thank Senator EDWARD KENNEDY of Massachusetts and Senator ORIN HATCH of Utah for their leadership on other法案 measures that reside in the other Chamber.

Again, I would thank everyone for participating in the debate. I urge my
colleagues’ strong approval of both bills before us, H.R. 4013 and H.R. 4014, as we proceed on these important measures today.

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

Mr. Speaker, I want to use this opportunity to take a historical perspective on some of these issues with regard to the pharmaceutical industry.

Mr. Speaker, I think that the pharmaceutical industry could be credited with the enormous contribution they make to finding diseases. But I think we need to recognize that when the Orphan Drug Act was first talked about, it was due to the fact that the pharmaceutical industry did not pay attention to people who had rare diseases because the profit potential was not there for them to make the investment. They were much more interested, as any business would be, in trying to manufacture drugs that could have a widespread audience, so to speak, to buy their products.

A lot of the work they do is based on the government investment and research. We give money to the National Institutes of Health, and they work with grants and contracts with leading researchers all around the country to do the basic work. The pharmaceutical industry then takes the benefit of that public investment and finds an application which leads to products that they are able to market. They then get a patent on the product. I have always regarded the purpose of the patent not to get its share of the return on our investment for some of these very same products.

But in the Orphan Drug Act we said, look, we will give you every incentive in the pharmaceutical industry to make the investment because we want people with rare diseases not to be ignored. So we gave them an exclusivity. If they developed a drug for patients with rare diseases, we gave them tax breaks. We funded research as this bill and the previous one will do at the NIH and at the FDA, but we found that while in most cases it barely offered any real profit numbers to be attractive to pharmaceutical industries, they responded well to the incentives.

In some cases, there were diseases that were classified as rare diseases which became a windfall for the pharmaceutical industry. The pharmaceutical industry, for example, when the HIV/AIDS epidemic hit, were able to classify their drugs as orphan drugs because the patient population was not that at that time.

Later it mushroomed, of course, as the epidemic progressed, and the Congress revisited the issues through hearings as to whether we were being too generous to the pharmaceutical industry in giving them the exclusivity which was the carrot.

We were willing to give them exclusivity for a disease that did not offer much profit potential, but when it was extremely profitable, there was not really any justification for that exclusivity over and above their patents and other rights that pharmaceutical manufacturers have. But we have never been able to take anything back from the drug companies once they have gotten it. It was not justified for them to have it.

There was another example of this, by the way, earlier this year. I was involved in the original legislation to say to the manufacturers, do the research on children when they get a drug approved, do that research so that we can know what the needs are for children, if they could use a certain pharmaceutical product. We tried to use a carrot and a stick. A stick would be if they were coming up with a new drug, FDA should require those tests before it approved the new drug, but a carrot for those drugs that are already on the market, we gave them an exclusivity of 6 months. Does not sound like a lot of time.

Then when we revisited the issue, it turned out that the companies were using that exclusivity in a way to enhance their monopoly over drugs that are widely used even though the studies on children are simply a way to keep out competition, and we know what happens when there is no competition. It means consumers pay the highest prices.

So we have some pharmaceuticals where there are wonderful drugs, the public investment in research paid off when they were applied by the pharmaceutical industry to the drugs, but it meant that some consumers could not even afford the drugs that were developed.

This bill before us today is a good one. We want to encourage the development of drugs for rare diseases, and I commend the drug companies for their work, but we need to keep it in perspective, that sometimes we have to come back and review these special breaks that we give to the companies because, there are some holes in the hole and expand it so enormously that it outpaces many consumers for their product. We want to give them the incentive to develop the product, but we want to let the public be able to purchase the product when possible.

I take these few minutes to give some expansion of the historical perspective on the Orphan Drug Act, the pediatric exclusivity, and we will save for another time the abuses the Hatch-Waxman Act, which we, hopefully we will keep an eye on. We are going to try to end by following the example of the U.S. Senate in stopping the loopholes that have been so abused by pharmaceutical companies, far beyond anything that any of us ever envisioned when we adopted the original Hatch-Waxman Act.

I ask my colleagues to join me in supporting this legislation.

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

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

I appreciate my colleague’s historical background. I am a relatively new Member still, in many ways and I know there is a lot of water under the bridge on a lot of these issues, and it is always good to look back.

He has been a leader and has been helpful on orphan drugs and pediatric exclusivity, and I am proud to have a chance to work with him on this legislation. I look forward to the opportunity to work with him more in the rare diseases. And I do try to get back to the point that all our citizens in this country have access to affordable health care.

Mr. DINGELL. Mr. Speaker, I am proud to be an original cosponsor of the bill before us today, H.R. 4014, the "Rare Diseases Orphan Product Development Act of 2002." I would like to thank my colleagues, particularly Representatives WAXMAN, BROWN, and RUSH, for their work on this legislation.

Approximately 25 million Americans suffer from more than 6,000 rare diseases. These diseases include Huntington’s disease, Lou Gehrig’s disease, cystic fibrosis, and Duchenne muscular dystrophy. Because of the relatively small patient populations associated with rare diseases, pharmaceutical firms are not always able to receive an adequate return on their investments in developing medications to treat them.

In response to this problem, Congress passed the Orphan Drug Act, which allows for market exclusivity for products developed for rare diseases. Additionally, the Food and Drug Administration (FDA) has been able to support small clinical trials through Orphan Products Research Grants. These grants have been effective, leading to the development of more than 23 drugs and four medical devices for rare diseases.

The purpose of this legislation is to increase the national investment in the development of diagnostics and treatments for patients suffering from rare diseases. H.R. 4014 continues the Orphan Products Research Grant program for clinical research needed to evaluate the safety and efficacy of therapies to treat rare diseases. Specifically, this legislation authorizes such sums as already have been appropriated for fiscal year 2002, and $25 million for each of the fiscal years 2003 through 2006.

This is good legislation. I urge my colleagues to join me and support H.R. 4014.

Mr. BILIRAKIS. Mr. Speaker, I am also pleased today to support H.R. 4014, the Rare Diseases Orphan Product Development Act of 2002. This bill, which was introduced by our colleague from Florida, Mr. FOLEY, will ensure that cutting-edge treatments are available for a myriad of rare diseases.

Specifically, H.R. 4014 will increase funding for the Food and Drug Administration’s Orphan Product Research Grants Program. This can encourage foreign and domestic scientists and small companies to conduct clinical trials on new orphan drugs, medical devices, and medical foods for rare diseases.
By definition, “orphans products” are treat-
ments for rare conditions that have small po-
tential markets and thus are not attractive in-
vestments for the private sector. Such treat-
ments were not being developed for rare dis-
eases until the Orphan Drug Act was enacted in
1983, and it has become a highly success-
ful government/industry partnership. Prior to
1983, only ten orphan products had come to
the market, while more than 200 drugs and bi-
ological products for rare diseases have been
brought to market since passage of the Or-
phan Drug Act.

H.R. 5091 ensures that adequate funding is
available for the development of orphan pro-
ducts. I commend my colleagues for their bипar-
sian efforts in this area and look forward to
voting for this legislation.

Mr. SHIMKUS. Mr. Speaker, I have
no other speakers on my side, and I
yield back the balance of my time.

The SPEAKER pro tempore (Mr.
BOOZMAN). The question is on the
motion offered by the gentleman from Illi-
nois (Mr. SHIMKUS) that the House sus-
pend the rules and pass the bill, H. R. 4014.

The question was taken.

The SPEAKER pro tempore. In the
opinion of the Chair, two-thirds of those present have voted in the affir-
mative.

Mr. WAXMAN. 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. Pursuant
to clause 8, rule XX and the Chair’s
prior announcement, further pro-
ceedings on this motion will be post-
poned.

The point of no quorum is considered
drawn.

CANCELING LOANS TO ALLOW
SCHOOL SYSTEMS TO ATTRACT
CLASSROOM TEACHERS ACT

Mr. MCECKON. Mr. Speaker, I move
to suspend the rules and pass the bill (H. R. 5991) to increase the amount of student loan forgiveness available to
qualified teachers, with an emphasis on
special education teachers, as amend-
ed.

The Clerk read as follows:

H.R. 5991
Be it enacted by the Senate and House of Rep-
resentatives of the United States of America in
Congress assembled.

SECTION 1. SHORT TITLE.

This Act may be cited as the “Canceling
Loans to Allow School Systems to Attract
Classroom Teachers Act”.

SEC. 2. ADDITIONAL QUALIFIED LOAN AMOUNTS
FOR STUDENT LOAN FORGIVENESS.

(a) FELLOWSHIPS LOANS.—Section 428(J)(c)
of the Higher Education Act of 1965 (20 U.S.C. 1078-
10(c)) is amended by adding at the end the follow-
ing new paragraph:

“(3) ADDITIONAL AMOUNTS; PRIORITY.—

“(A) LARGER AMOUNTS FROM APPROPRIATED
FUNDS.—Notwithstanding the amount speci-
fied in paragraph (1), the aggregate amount
that the Secretary may, from funds appro-
priated under paragraph (c), repay under
this section is a total amount equal to not
more than $17,500.

“(B) AWARD BASIS; PRIORITY.—The Sec-
retary shall make payments under this para-
graph to elementary or secondary school
teachers who meet the requirements of sub-
section (b) on a first-come first-served basis,
subject to the availability of appropriations,
but shall give priority in providing loan re-
payment under this paragraph for a fiscal
year to teachers who

“(i) are employed as special education
teachers whose primary responsibility is to
 teach or support children with disabilities
(defined in section 1112(a) of the Indivi-
duals with Disabilities Act); and

“(ii) as certified by the chief adminis-
trative officer of a public or nonprofit pri-
elementary or secondary school in which
the borrower is employed, are teaching
children with disabilities that correspond with
the borrower’s training and have demon-
strated knowledge and teaching skills in the con-
tent areas of the elementary or secondary
school curriculum that the borrower is teaching;

“(C) AUTHORIZATION OF APPROPRIA-
TIONS.—There are authorized to be appro-
priated to the Secretary of Education for fiscal
year 2003 and for each fiscal year thereafter
such sums as may be necessary for carry-
out this section.

SEC. 3. CANCELLATION OF STUDENT LOAN IN-
DEBTEDNESS FOR SPOUSES, SUR-
VIVING JOINT DEBTORS, AND PARE-
NTS.

(a) DEFINITIONS.—For purposes of this sec-
tion:

(1) ELIGIBLE PUBLIC SERVANT.—The term
“eligible public servant” means an indi-
vidual who—

“A served as a police officer, firefighter,
other public safety or rescue person-
nel, or as a member of the Armed Forces; and

(2) DIED (or dies) or became (or becomes)
permanently and totally disabled due to in-
juries suffered in the terrorist attack on Sep-
tember 11, 2001,

as determined in accordance with regu-
lations of the Secretary.

(2) ELIGIBLE VICTIM.—The term “eligible
victim” means an individual who (died or
died or became (or becomes) perma-
nently and totally disabled due to injuries
suffered in the terrorist attack on Septem-
ber 11, 2001, as determined in accordance with regu-
lations of the Secretary.

(3) ELIGIBLE SPOUSE.—The term “eligible
spouse” means the spouse of an eligible pub-
lic servant, as determined in accordance with regu-
lations of the Secretary.

(4) ELIGIBLE SURVIVING DEBTOR.—The term
“eligible surviving debtor” means an indivi-
dual who owes a Federal student loan that
is a consolidation loan that was used, jointly
by that individual and an eligible victim, to
repay the Federal student loans of that indi-
vidual and of such eligible victim.

(5) ELIGIBLE PARENT.—The term “eligible
parent” means the parent of an eligible vic-
tim.

“An parent owes a Federal student
loan that is a consolidation loan that was
used to repay a PLUS loan incurred on be-
half of such eligible victim.

“(B) the parent owes a Federal student
loan that is a PLUS loan incurred on behalf
of an eligible victim who (becomes or
becomes) permanently and totally disabled due to
injuries suffered in the terrorist attack on Septem-

(6) SECRETARY.—The term “Secretary” means
the Secretary of Education.

(7) FEDERAL STUDENT LOAN.—The term
“Federal student loan” means any loan
made, insured, or guaranteed under part B,
D, or E of title IV of the Higher Education Act of
1965.

(b) RELIEF FROM INDEBTEDNESS.—

(1) IN GENERAL.—The Secretary shall
provide for the discharge or cancellation of—

(A) the Federal student loan indebtedness of an
eligible spouse;

(B) the consolidation loan indebtedness of an
eligible survivor;

(C) the portion of the consolidation loan
indebtedness of an eligible parent that was
incurred on behalf of an eligible victim, if
the result of such indebtedness with re-
spect to such eligible victim may be rea-
lly determined on the basis of records available
and

(D) the PLUS loan indebtedness of an eligi-
ble parent that was incurred on behalf of an
eligible victim described in subsection (a)(7).

(2) METHOD OF DISCHARGE OR CANCELLA-
TION.—A loan required to be discharged or
canceled under paragraph (1) shall be dis-
charged or canceled on a first-come first-
canceled basis, subject to the availability of
appropriations toward meeting the annual measur-
able objectives described in section 1119(a)(2) of
such Act for 2 consecutive years, or

(D) the PLUS loan indebtedness of an eligi-
ble parent that was incurred on behalf of an eligi-
ble victim described in subsection (a)(7).

(c) FACILITATION OF CLAIMS.—The Sec-
retary shall—

(1) establish procedures for the filing of ap-
pellations for discharge or cancellation under
this section by regulations that shall be
prescribed and published within 90 days

H6618
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October 1, 2002