recognizes the need for improved patient support, improved physician awareness and understanding, and more effective treatment, including finding a cure. Mr. Speaker, I urge my colleagues to support H. Con. Res. 291.

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

Mr. SHIMKUS. Mr. Speaker, 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 Illinois (Mr. SHIMKUS) that the House suspend the rules and agree to the concurrent resolution, House Concurrent Resolution 291.

The question was taken.

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

Mr. GREEN of Texas. 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 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

The point of no quorum is considered withdrawn.

RARE DISEASES ACT OF 2002

Mr. SHIMKUS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4013) to amend the Public Health Service Act to establish an Office of Rare Diseases at the National Institutes of Health, and for other purposes.

The Clerk read as follows:

H.R. 4013

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 ''Rare Diseases Act of 2002''.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

(1) Rare diseases and disorders are those which affect small patient populations, typically populations smaller than 200,000 individuals in the United States. Such diseases and conditions include Huntington's disease, amyotrophic lateral sclerosis (Lou Gehrig's disease), Tourette syndrome, Crohn's disease, cystic fibrosis, cystinosis, and Duchenne muscular dystrophy.

(2) For many years, the 25,000,000 Americans suffering from the over 6,000 rare diseases and disorders were denied access to effective medicines because prescription drug manufacturers could rarely make a profit from marketing drugs for such small groups of patients. The prescription drug industry did not adequately fund research into such treatments. Despite the urgent health need for these medicines, they came to be known as ''orphan drugs'' because no companies would commercialize them.

(3) During the 1970s, an organization called the National Organization for Rare Disorders (NORD) was founded to provide services and to lobby on behalf of patients with rare diseases and disorders. NORD was instrumental in pressing Congress for legislation to encourage the development of orphan drugs.

(4) The Orphan Drug Act created financial incentives for the research and production of such orphan drugs. New Federal programs at the National Institutes of Health and the Food and Drug Administration encouraged clinical research and commercial product development for products that target rare diseases. An Orphan Products Board was established to promote the development of drugs and devices for rare diseases or disorders.

(5) Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act, more than 220 new orphan drugs have been approved and marketed in the United States and more than 800 additional drugs are in the research pipeline.

(6) Despite the tremendous success of the Orphan Drug Act, rare diseases and disorders deserve greater emphasis in the national biomedical research enterprise. The Office of Rare Diseases at the National Institutes of Health was created in 1993, but lacks a statutory authorization.

(7) The National Institutes of Health has received a substantial increase in research funding from Congress for the purpose of expanding the national investment of the United States in behavioral and biomedical research.

(8) Notwithstanding such increases, funding for rare diseases and disorders at the National Institutes of Health has not increased appreciably.

(9) To redress this oversight, the Department of Health and Human Services has proposed the establishment of a network of regional centers of excellence for research on rare diseases.

(b) PURPOSES.—The purposes of this Act are to—

(1) amend the Public Health Service Act to establish an Office of Rare Diseases at the National Institutes of Health; and

(2) increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders.

SEC. 3. NIH OFFICE OF RARE DISEASES AT NATIONAL INSTITUTES OF HEALTH.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by Public Law 107–84, is amended by inserting after section 404E the following:

''OFFICE OF RARE DISEASES

''SEC. 404F. (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Rare Diseases (in this section referred to as the 'Office'), which shall be headed by a Director (in this section referred to as the 'Director'), appointed by the Director of NIH.

''(b) DUTIES.—

''(1) IN GENERAL.—The Director of the Office shall carry out the following:

''(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

''(B) The Director shall, with respect to rare diseases, promote coordination and cooperation among the national research institutes and centers and entities whose research is supported by such institutes.

''(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 404G.

''(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

''(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

''(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies particular projects or types of projects that should in the future be conducted or supported by the national research institutes and centers or other entities in the field of research on rare diseases.

''(G) The Director shall prepare the NIH Director's annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.

''(2) PRINCIPAL ADVISOR REGARDING ORPHAN DISEASES.—With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

''(c) DEFINITION.—For purposes of this section, the term 'rare disease' means any disease or condition that affects less than 200,000 persons in the United States.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $4,000,000 for each of the fiscal years 2003 through 2006.''.

SEC. 4. RARE DISEASE REGIONAL CENTERS OF EXCELLENCE.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 3, is further amended by inserting after section 404F the following:

''RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

''SEC. 404G. (a) COOPERATIVE AGREEMENTS AND GRANTS.—

''(1) IN GENERAL.—The Director of the Office of Rare Diseases (in this section referred to as the 'Director'), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

''(2) POLICIES.—A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

''(b) COORDINATION WITH OTHER INSTITUTES.—The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

''(c) USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

''(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

''(2) clinical training, including training for allied health professionals, continuing

education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

''(3) clinical research and demonstration programs.

''(d) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

''(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $20,000,000 for each of the fiscal years 2003 through 2006.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Illinois (Mr. SHIMKUS) and the gentleman from Texas (Mr. GREEN) each will control 20 minutes.

The Chair recognizes the gentleman from Illinois (Mr. SHIMKUS).

GENERAL LEAVE

Mr. SHIMKUS. 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 this legislation.

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

There was no objection.

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

Mr. Speaker, I would like to commend the distinguished gentleman from Louisiana (Chairman TAUZIN) and my good friend, the gentleman from Florida (Mr. FOLEY), for their work in bringing attention to rare diseases and disorders.

In the United States today, one in nine Americans suffer from a known rare disease or disorder for which there is often no good treatment or cure. The legislation sponsored by my colleagues works to correct that problem. Taken together, the Rare Diseases Act and its companion bill, the Rare Disease Orphan Product Development Act, encourage the development of better treatments, diagnostic procedures, and cures for large numbers of rare diseases and disorders.

There are over 6,000 known rare diseases, and although each of them individually affects less than 200,000 people, the total number of Americans affected is over 25 million people. These acts build on the success of the Orphan Drug Act of 1983, which has led to the development of over 220 treatments for rare diseases and disorders, including Huntington's disease, Lou Gehrig's disease, and Tourette syndrome.

Still, patients with rare diseases continue to face challenges in receiving appropriate and adequate treatment. The National Commission on Orphan Diseases estimated that only one-third of patients receive an accurate diagnosis in the 3 to 5 years after the onset of symptoms, and 50 percent of the population is not accurately diagnosed until 7 or more years after the onset of symptoms.

Research into rare diseases and disorders provides hope for thousands of Americans and their families. This legislation does not detract from other worthy congressional research priorities of the NIH, such as the Children's Health Act of 2000. Instead, these bills increase funding for two programs that have already had a direct and positive impact on this community. They expand and enhance existing research under way at various institutes of the NIH.

Again, I am pleased to support passage of these two pieces of legislation and stand ready to work with my esteemed colleagues to ensure that they are enacted into law.

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 rise in support of H.R. 4013, the Rare Diseases Act of 2002. I am proud to have introduced this piece of legislation with my colleague, the gentleman from Illinois (Mr. SHIMKUS). This is a bill which would work to the benefit of those suffering from rare diseases both by establishing an Office of Rare Diseases at the National Institutes of Health, and by providing for rare disease regional centers of excellence.

A rare disease is defined in the United States as one affecting fewer than 200,000 Americans. There are around 6,000 known rare diseases, and it is estimated that about 25 million Americans are affected by them. Over 220 treatments have been developed in the last two decades for rare diseases, but many more are needed.

The Office of Rare Diseases at the National Institutes of Health was established in 1993 to promote research and provide information. However, this office was not given any authority. Also, although Congress has substantially increased research funding for NIH, funding for rare diseases has only increased slightly. This legislation increases to $25 million the Orphan Product Research Grant Program administered by the Office of Orphan Product Development at the Food and Drug Administration, thus encouraging more extensive research, testing, and attention.

The Rare Diseases Act of 2002 establishes the Office of Rare Diseases as a Federal office, including its ability to coordinate research and establish regional centers of excellence for clinical research.

This is an important piece of legislation, and I urge all my colleagues to join me in supporting its passage.

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

Mr. SHIMKUS. Mr. Speaker, I yield such time as he may consume to the gentleman from Florida (Mr. FOLEY), who has been an ardent spokesperson and supporter of this legislation.

Mr. FOLEY. Mr. Speaker, I thank the gentleman for yielding time to me. I thank the gentleman from Illinois (Mr. SHIMKUS) for his leadership on these very important pieces of legislation today, as well as the gentleman from California (Mr. WAXMAN) for his many, many years of outstanding service on the Subcommittee on Health.

Mr. Speaker, many people are unfamiliar with some of the diseases that were mentioned earlier. Today in Palm Beach County, there are a lot of diseases that have tremendous charity organizations helping to support them, to raise money. In fact, there is a ball a day that is pretty much dedicated to raising resources and to not only find research dollars, but hopefully find cures for diseases that ravage mankind, but most all of them are popular and well known. They may be AIDS, Alzheimer's, things that people are well familiar with.

Regrettably, the rare diseases do not have the same fan club. They do not have the same outreach, and they certainly do not have the same support network as some of the bigger charities are fortunate to have in my district and throughout the country. That is why it is critically important to pass both of these pieces of legislation today, because they create the framework to bring about an educational process, to create the framework to channel resources into the National Institutes of Health and other entities in order to find the potential cures, as well as the subsequent bill we will talk about that helps to provide, if you will, the kind of dollars necessary for pharmaceutical companies and others to be able to pursue what is not a profitable research path, but is a research path, nonetheless, that yields great results to the person suffering.

So again, I commend the gentleman from Illinois (Mr. SHIMKUS), and I am certain the citizens of Illinois appreciate the fact that he is on this very important subcommittee of the Committee on Commerce dealing with the health care of many millions of Americans who are silent on the floor today, but are watching with great anticipation as we hopefully unlock the key to one of the many doors that block some of the research available.

Hopefully with these bills we will see an outpouring of support not only into research endeavors, but also into long-term sustainability of the lives of these very important Americans we are speaking about today.

Mr. WAXMAN. Mr. Speaker, I am pleased to yield such time as he may consume to the gentleman from Illinois (Mr. DAVIS).

Mr. DAVIS of Illinois. Mr. Speaker, I want to, first of all, thank the gentleman from California (Mr. WAXMAN) for yielding time to me, and commend him and the gentleman from Illinois (Mr. SHIMKUS) for introducing this legislation.

I also want to thank the former commissioner of the Chicago Metropolitan Water Reclamation District, the distinguished JoAnn Alter, for bringing this matter to my attention. Therefore, I rise in support of H.R. 4013, the Rare Diseases Act of 2002.

Mr. Speaker, with a large low-income population, 24 hospitals, 5 medical schools, and several research institutions in my district, I know firsthand the heartbreak faced by people who struggle to find the appropriate medical treatment for themselves and their families.

We have made tremendous strides in education, research, and medical protocols for individuals with diseases that affect large populations. Much funding has been dedicated and continues to be directed to treatment of diseases such as cancer, heart disease, and diabetes, and this is all good.

There are, however, a number of rare diseases which affect 200,000 or fewer Americans which continue to go underresourced. While statistically 200,000 people may be a small number, it is a large number when we consider it represents people needing medical treatment. However, if we aggregate the number of people suffering from at least 1 of the 6,000 known rare diseases and disorders, we are talking about 25 million Americans, 1 in 9, suffering from a rare disease.

Several months ago a mother and her young son, who suffers from Crohn's disease, traveled hundreds of miles from Virginia to Northwestern Memorial Hospital in my district to see if he could be accepted into a special treatment program that was offered nowhere near his home. He wrote a letter to me thanking me for the fact that he was indeed able to get into Northwestern and to be considered for treatment for his very rare disease.

This bill, H.R. 4013, which establishing an Office of Rare Diseases at the National Institutes of Health, by increasing the national investment in the development of diagnostics and treatment for patients with rare diseases and disorders, and by allowing for rare disease regional centers of excellence, is a quantum leap in the right direction. I again commend my colleagues for its introduction and urge swift passage of this resolution.

□ 1330

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

Mr. KIRK. Mr. Speaker, I rise today in strong support of H.R. 4013, the Rare Disease Act of 2002. Currently, more than 6,000 rare diseases affect 25 million Americans each year. While some progress has been made to fight rare diseases over the last twenty years, we must commit greater resources to this effort, particularly through the National Institutes of Health.

My own constituents have been very active in this fight. Families of Spinal Muscular Atrophy, based in Libertyville, Illinois, have been working to enhance research efforts of this and other rare diseases since 1984. I commend Audrey Lewis and all of the Families of SMA's staff and volunteers for their continued dedication and hard work in this field.

SMA is just one of the thousands of rare diseases that continues to impact American families, and is the number one genetic killer of children under the age of two. A child of parents who both carry the SMA gene has a one in four chance of developing this devastating disease. Inflicted children are forced to live with neuromuscular deterioration that can affect crawling, walking, head control and swallowing.

We must make every effort to expand research efforts so that those with SMA and other rare diseases have a change to live long and healthy lives. I hope that Congress can send a united message of the importance of enhanced research efforts in this field by supporting this bill. An Office of Rare Diseases at the National Institutes of Health is an essential element in our efforts to raise awareness and research for SMA and the thousands of other rare diseases affecting Americans. I urge my colleagues to support H.R. 4013.

Mr. PITTS. Mr. Speaker, the legislation before us today represents the latest steps in Congress' twenty year commitment to Americans with rare ''orphan'' diseases. Since its passage in 1983, the Orphan Drug Act has stimulated the development of 231 new marketed orphan products, with several hundred more in the pipeline for which we all have great hopes. Yet, there are still more than 5,000 rare diseases with no specialized treatment at all. For this reason, H.R. 4013 and H.R. 4014 represent major advances in stimulating new therapies for those with rare diseases, as well as improved care.

It is important to note, however, that even those 231 marketed orphan drugs, biologics, foods and devices are not always readily available to patients because of geographical and insurance barriers. One of the unfinished pieces of business facing this Congress is to make sure that Medicare is not contributing to this problem.

Three years ago, when Congress created the Medicare Hospital Outpatient Prospective Payment System, known as HOPPS, Congress placed all orphan products into a pass-through category where they would be paid at a higher rate. Even still, many hospitals have lost money when they stocked orphan drugs to treat patients with rare diseases.

Now we are faced with a situation where CMS has proposed a regulation for the 2003 HOPPS program that leaves most orphan drugs, biologicals and blood plasma therapies and their recombinant analogs such as clotting factors for individuals with Hemophilia without adequate reimbursement. Many hospitals will refuse to stock these drugs because of the large loss they will incur for treating a small number of patients. Without appropriate reimbursement, patients may be turned away from hospital emergency rooms or directed to alternative facilities if the location does not stock their product. The consequences of inadequate or non-existent access would be devastating, particularly in rural areas where the nearest hospital to stock a particular orphan drug may be a hundred or more miles away.

Mr. Speaker, it is critical that the House of Representatives act this year to ensure that orphan drugs are properly reimbursed.

Mr. KIND. Mr. Speaker, I rise in support of both the Rate Diseases Act (H.R. 4013) and Rare Diseases Orphan Product Development Act (H.R. 4014). A rare disease is defined as one that afflicts fewer than 200,000 individuals. Our country has over 6,000 rare diseases that affect more than 25 millions Americans.

Both of these measures will provide necessary incentives to find a cure for these ailments. H.R. 4013 establishes an Office of Rare Diseases within the National Institutes of Health director's office. In addition, the bill creates Rare Disease Regional Centers of Excellence to conduct research and training in the diagnosis, prevention, control and treatment of rare diseases. H.R. 4014 would double the funding to $25 million for the successful FDA grant program for research on orphan drugs. Since 1983, the FDAa has approved more than 200 treatments for rare diseases, this additional funding will be critical to increasing the number of treatments available.

A wonderful family in my hometown, the Kirches, brought the issue of rare diseases to my attention. I have had the opportunity to meet with Larry, Susan and their daughter Allyson to hear about their struggles and triumphs with Allyson's battle with Mucopolysachharidosis (MPS) III. MPS III is a genetic disorder that results in the body's inability to produce certain enzymes. This lack of enzyme production interrupts the usual breakdown of complex carbohydrates that are stored in almost every cell in the body. Without the breakdown, storage progressively builds in each cell causing damage in multiple systems within the body including respiratory, bones, internal organs, and nervous system. The results of this damage include mental retardation, short stature, cornea damage, loss of mobility, and most importantly a drastically shortened life span. At present there is no cure for MPS III.

Allyson's future depends on investment in scientific and biomedical research by the public and private sector and, we owe it to all children with these disorders to make every effort to improve their quality of life and ultimately contribute to efforts in developing effective treatments. I urge my colleagues to support these measures and assist families like the Kirches all across our country.

Mr. DINGELL. Mr. Speaker, I rise in strong support of H.R. 4013, the ''Rare Diseases Act of 2002,'' of which I am proud to be an original cosponsor. I would like to thank my colleagues on both sides of the aisle for working together to introduce this important legislation and for working on behalf of the 25 million American people who suffer from rare diseases.

Rare, or orphan diseases affect fewer than 200,000 individuals in America. Nearly one million people in my home state of Michigan are afflicted with a rare disease. There are more than 6,000 rare diseases. Enactment of the Orphan Drug Act of 1983 provided incentives for drug and biological manufacturers to invest in treatment for rare diseases.

While the Orphan Drug Act has achieved dramatic increases in research into, and treatments for rare diseases, more still needs to be done. One positive step includes authorizing, in statute, the Office of Rare Diseases.

In addition, H.R. 4013 authorizes regional centers of excellence for rare disease research. This will enable the National Institutes of Health (NIH) to select sites to concentrate on finding cures and treatment methods for rare diseases.

I urge all of my colleagues to join me in support of H.R. 4013.

Mr. BILIRAKIS. 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 piece of 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.

The SPEAKER pro tempore (Mr. BOOZMAN). The question is on the motion offered by the gentleman from Illinois (Mr. SHIMKUS) that the House suspend the rules and pass the bill, H.R. 4013.

The question was taken.

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

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 proceedings on this motion will be postponed.

The point of no quorum is considered withdrawn.

RARE DISEASES ORPHAN PRODUCT DEVELOPMENT ACT OF 2002

Mr. SHIMKUS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4014) to amend the Federal Food, Drug, and Cosmetic Act with respect to the development of products for rare diseases.

The Clerk read as follows:

H.R. 4014

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 ''Rare Diseases Orphan Product Development Act of 2002''.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

(1) Rare diseases and disorders are those which affect small patient populations, typically populations smaller than 200,000 individuals in the United States. Such diseases and conditions include Huntington's disease, amyotrophic lateral sclerosis (Lou Gehrig's disease), Tourette syndrome, Crohn's disease, cystic fibrosis, cystinosis, and Duchenne muscular dystrophy.

(2) For many years, the 25,000,000 Americans suffering from the over 6,000 rare diseases and disorders were denied access to effective medicines because prescription drug manufacturers could rarely make a profit from marketing drugs for such small groups of patients. The prescription drug industry did not adequately fund research into such treatments. Despite the urgent health need for these medicines, they came to be known as ''orphan drugs'' because no companies would commercialize them.

(3) During the 1970s, an organization called the National Organization for Rare Disorders (NORD) was founded to provide services and to lobby on behalf of patients with rare diseases and disorders. NORD was instrumental in pressing Congress for legislation to encourage the development of orphan drugs.

(4) The Orphan Drug Act created financial incentives for the research and production of such orphan drugs. New Federal programs at the National Institutes of Health and the Food and Drug Administration encouraged clinical research and commercial product development for products that target rare diseases. An Orphan Products Board was established to promote the development of drugs and devices for rare diseases or disorders.

(5) Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act, more than 220 new orphan drugs have been approved and marketed in the United States and more than 800 additional drugs are in the research pipeline.

(6) Despite the tremendous success of the Orphan Drug Act, rare diseases and disorders deserve greater emphasis in the national biomedical research enterprise.

(7) The Food and Drug Administration supports small clinical trials through Orphan Products Research Grants. Such grants embody successful partnerships of government and industry, and have led to the development of at least 23 drugs and four medical devices for rare diseases and disorders. Yet the appropriations in fiscal year 2001 for such grants were less than in fiscal year 1995.

(b) PURPOSES.—The purpose of this Act is to increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders.

SEC. 3. FOOD AND DRUG ADMINISTRATION; GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.

Subsection (c) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

''(c) For grants and contracts under subsection (a), there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $25,000,000 for each of the fiscal years 2003 through 2006.''.

SEC. 4. TECHNICAL AMENDMENT.

Section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is amended in the matter following paragraph (2)—

(1) by striking '', of such certification,''; and

(2) by striking '', the issuance of the certification,''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Illinois (Mr. SHIMKUS) and the gentleman from California (Mr. WAXMAN) each will control 20 minutes.

The Chair recognizes the gentleman from Illinois (Mr. SHIMKUS).

GENERAL LEAVE

Mr. SHIMKUS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and to insert extraneous material on the bill, H.R. 4014.

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

There was no objection.

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

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 the legislative battles and the agenda. 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 really 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 cures 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 it makes you 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 totalling in the thousands. That is why prior to 1983 only 38 drugs had been developed for rare diseases.