SEC. 2. REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study investigating the extent to which sponsors of clinical studies of investigational drugs, biologics, and devices and sponsors of applications for approval or licensure of new drugs, biologics, and devices comply with Food and Drug Administration requirements and follow guidance for presentation of clinical study safety and effectiveness data by sex, age, and racial subgroups.

(b) REPORT BY GAO.—

(1) SUBMISSION.—Not later than 12 months after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the results of such study.

(2) CONTENTS.—The report required by paragraph (1) shall include each of the following:

(A) A description of the extent to which the Food and Drug Administration assists sponsors in complying with the requirements and following the guidance referred to in subsection (a).

(B) A description of the effectiveness of the Food and Drug Administration's enforcement of compliance with such requirements.

(C) An analysis of the extent to which females, racial and ethnic minorities, and adults of all ages are adequately represented in Food and Drug Administration-approved clinical studies (at all phases) so that product safety and effectiveness data can be evaluated by gender, age, and racial subgroup.

(D) An analysis of the extent to which a summary of product safety and effectiveness data disaggregated by sex, age, and racial subgroup is readily available to the public in a timely manner by means of the product label or the Food and Drug Administration's Website.

(E) Appropriate recommendations for—

(i) modifications to the requirements and guidance referred to in subsection (a); or

(ii) oversight by the Food and Drug Administration of such requirements.

(c) REPORT BY HHS.—Not later than 6 months after the submission by the Comptroller General of the report required under subsection (b), the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a response to that report, including a corrective action plan as needed to respond to the recommendations in that report.

(d) DEFINITIONS.—In this section:

(1) The term ''biologic'' has the meaning given to the term ''biological product'' in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(2) The term ''device'' has the meaning given to such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(3) The term ''drug'' has the meaning given to such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

SEC. 3. REPORTING ON QUALITY OF AND ACCESS TO CARE FOR WOMEN WITH CARDIOVASCULAR DISEASES.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

''SEC. 399V–5. REPORTING ON QUALITY OF AND ACCESS TO CARE FOR WOMEN WITH CARDIOVASCULAR DISEASES.

''Not later than September 30, 2013, and annually thereafter, the Secretary of Health and Human Services shall prepare and submit to the Congress a report on the quality of and access to care for women with heart disease, stroke, and other cardiovascular diseases. The report shall contain recommendations for eliminating disparities in, and improving the treatment of, heart disease, stroke, and other cardiovascular diseases in women.''.

SEC. 4. EXTENSION OF WISEWOMAN PROGRAM.

Section 1509 of the Public Health Service Act (42 U.S.C. 300n–4a) is amended—

(1) in subsection (a)—

(A) by striking the heading and inserting ''IN GENERAL.—''; and

(B) in the matter preceding paragraph (1), by striking ''may make grants'' and all that follows through ''purpose'' and inserting the following: ''may make grants to such States for the purpose''; and

(2) in subsection (d)(1), by striking ''there are authorized'' and all that follows through the period and inserting ''there are authorized to be appropriated $23,000,000 for fiscal year 2012, $25,300,000 for fiscal year 2013, $27,800,000 for fiscal year 2014, $30,800,000 for fiscal year 2015, and $34,000,000 for fiscal year 2016.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Texas (Mr. BURGESS) 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 in which to revise and extend their remarks and include extraneous material in the RECORD.

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

There was no objection.

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

I rise today in strong support of H.R. 1032, the HEART for Women Act. Heart disease is the number one killer of women, and stroke is the number three killer of women. H.R. 1032 expands the CDC's Wise Women Program, which serves low-income, uninsured, and underinsured women by providing cardiovascular disease screenings, referrals, outreach, and education about healthy behaviors.

I urge my colleagues to support this legislation.

I reserve the balance of my time.

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

H.R. 1032, the Heart Disease Education, Analysis, Research, and Treatment for Women Act, would take several important steps in the fight against heart disease, stroke, and other cardiovascular diseases.

First, the amended bill would require the Government Accountability Office to conduct a study on the extent to which sponsors of new drugs, biologics, and devices follow current guidelines with respect to providing clinical trial data by gender and ethnicity. It would also require the Secretary to submit a report to Congress by September 30, 2013, and annually thereafter on the quality and access to care for women with heart disease, stroke, and other cardiovascular disease. Finally, the bill would reauthorize the Wise Women Program for 5 years. The program provides preventative benefits to uninsured and underinsured women who are at high risk of heart disease.

I urge my colleagues to support the bill.

Mrs. CAPPS. Mr. Speaker, I rise in strong support of H.R. 1032, the HEART for Women Act. As you may know, heart disease is the number one killer of American women, claiming the lives of over 400,000 women annually.

The HEART for Women Act seeks to improve our capability to prevent, diagnose and treat heart disease in women in three ways.

First, it requires a GAO report to carefully look at the FDA's record of evaluating new drug and device applications in an effort to ensure we are taking into account how new drugs and devices affect women differently than men as well as people of different ethnicities or ages.

This could not be more timely following the recently released Institute of Medicine report "Women's Health Research: Progress, Pitfalls, and Promise" recommending that "all medical product evaluations by the Food and Drug Administration present efficacy and safety data separately for men and women. . ."

Second, the bill requires the Secretary to report on the quality and access to care for women with heart disease, stroke and other cardiovascular disease.

And finally, it expands the CDC's successful WISEWOMAN program which provides critical cardiovascular screening, treatment, education and prevention services to low-income women.

I'd like to thank the broad coalition of supporters who have endorsed this legislation, especially American Heart Association, WomenHeart and the Society for Women's Health Research.

I urge my colleagues to vote in favor of this legislation and in favor of improving the health of women living with heart disease.

Mr. BURGESS. I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I urge passage of the bill, and 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 bill, H.R. 1032, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. BURGESS. 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.

SCLERODERMA RESEARCH AND AWARENESS ACT OF 2010

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2408) to expand the research and awareness activities of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and the

Centers for Disease Control and Prevention with respect to scleroderma, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 2408

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 ''Scleroderma Research and Awareness Act of 2010''.

SEC. 2. NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; SCLERODERMA RESEARCH EXPANSION.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

''SEC. 409K. SCLERODERMA RESEARCH.

''The Director of NIH may expand, intensify, and coordinate the activities of the National Institutes of Health with respect to scleroderma, with particular emphasis on the following:

''(1) Research focused on the etiology of scleroderma and the development of new treatment options.

''(2) Clinical research to evaluate new treatments options.

''(3) Basic research on the relationship between scleroderma and secondary conditions such as pulmonary hypertension, gastroparesis, Raynaud's phenomenon, Sjögren's Syndrome, and other diseases as determined by the Director.''.

SEC. 3. PROMOTING PUBLIC AWARENESS OF SCLERODERMA.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

''SEC. 399V–5. PROMOTING PUBLIC AWARENESS OF SCLERODERMA.

''The Secretary may carry out an educational campaign to increase public awareness of scleroderma. Print, video, and Web-based materials distributed through this campaign may include—

''(1) basic information on scleroderma and its symptoms; and

''(2) information on—

''(A) the incidence and prevalence of scleroderma;

''(B) diseases and conditions affiliated with scleroderma; or

''(C) the importance of early diagnosis and treatment of scleroderma.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Texas (Mr. BURGESS) 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 in which to revise and extend their remarks and include extraneous material in the RECORD.

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 rise today in strong support of H.R. 2408, the Scleroderma Research and Awareness Act. H.R. 2408 would encourage NIH to conduct more research into scleroderma and encourage HHS to conduct a public awareness campaign about scleroderma. I urge my colleagues to support this legislation.

I reserve the balance of my time.

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

H.R. 2408, the Scleroderma Research and Awareness Act, would expand research and education for scleroderma. There are an estimated 300,000 people in the United States who have this disease. The exact cause or causes of scleroderma are still unknown, but scientists and medical investigators in a wide variety of fields are working to make those determinations.

Scleroderma, or systemic sclerosis, is a chronic connective tissue disease generally classified as one of the autoimmune rheumatic diseases. This bill will provide the Department of Health and Human Services flexibility to help us in the fight against scleroderma in the following ways: First, the bill would allow but not require the director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health to expand, intensify, and coordinate the activities of the institute with respect to scleroderma. Second, the amended bill would allow but not require the Health and Human Services Secretary, acting through the Centers for Disease Control, to carry out an educational campaign to increase public awareness of scleroderma.

This bill underwent some very important modifications at the committee level. I think it is a better bill for that bipartisan effort. I do urge my colleagues to support this legislation.

Mrs. CAPPS. Mr. Speaker, I rise in strong support of H.R. 2408, the Scleroderma Research and Awareness Act.

Scleroderma is a chronic connective tissue disease in which hardening of the skin is one of the most visible manifestations of the disease.

An estimated 300,000 people in the United States have scleroderma and female patients outnumber male patients an astonishing four to one.

The exact cause or causes of scleroderma are still unknown and there is no cure, which make greater research into this disease all the more necessary.

H.R. 2408 would encourage NIH to conduct more research into Scleroderma and encourage the Secretary of Health & Human Services to conduct a public awareness campaign about the disease.

Passage of this bill out of Committee and in the House of Representatives would not be possible without the grassroots advocacy of patients and families of patients with Scleroderma so I would like to thank them personally for helping us reach today.

Finally, I would like to thank the lead Republican co-sponsor of this legislation, VERN EHLERS of Michigan for his continued support of H.R. 2408.

I urge my colleagues to vote in favor of this bill.

Mr. BURGESS. I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I urge passage of the bill, and 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 bill, H.R. 2408, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. BURGESS. 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.

NEGLECTED INFECTIONS OF IMPOVERISHED AMERICANS ACT OF 2010

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5986) to require the submission of a report to the Congress on parasitic disease among poor Americans.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5986

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 ''Neglected Infections of Impoverished Americans Act of 2010''.

SEC. 2. REPORT TO CONGRESS ON THE CURRENT STATE OF PARASITIC DISEASES THAT HAVE BEEN OVERLOOKED AMONG THE POOREST AMERICANS.

(a) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall report to the Congress on the epidemiology of, impact of, and appropriate funding required to address neglected diseases of poverty, including neglected parasitic diseases such as—

(1) Chagas disease;

(2) cysticercosis;

(3) toxocariasis;

(4) toxoplasmosis;

(5) trichomoniasis;

(6) the soil-transmitted helminths; and

(7) other related diseases, as designated by the Secretary.

(b) REQUIRED INFORMATION.—The report under subsection (a) should provide the information necessary to guide future health policy to—

(1) accurately evaluate the current state of knowledge concerning diseases described in such subsection and define gaps in such knowledge; and

(2) address the threat of such diseases.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Texas (Mr. BURGESS) 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 in which to revise and extend their remarks and include extraneous material in the RECORD.