and patients about their benefits, we can increase adoption of these lower cost alternative therapies when appropriate and drive down drug costs for Americans across the country.

Mr. Speaker, I urge support for this bipartisan effort to lower drug costs through the uptake of biosimilar products, and I reserve the balance of my time.

□ 1315

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

Mr. BILIRAKIS. Mr. Speaker, I yield such time as he may consume to the gentleman from Indiana (Mr. BUCSHON), a great member of the Energy and Commerce Committee and a great resource for us nonphysicians.

Mr. BUCSHON. Mr. Speaker, I would like to speak in support of S. 164, the Advancing Education on Biosimilars Act of 2021, which is the Senate companion of H.R. 1873, a bill that I introduced with my friend and colleague, Congressman SCOTT PETERS from California.

This bipartisan, bicameral bill will require FDA to create a public website to educate patients and providers about biological and biosimilar products.

As new biological and biosimilar products become available, it is important that physicians have current information on these therapies in order to choose the best treatment for their patients.

Availability of information and education on these new and complex treatments for providers and patients will lead to healthy competition in the biologic and biosimilar product space and ultimately help to lower the cost of these important drugs for patients.

I urge my colleagues to support this bill, and I look forward to the President signing it into law.

Mr. PALLONE. Mr. Speaker, I have no additional speakers.

Mr. BILIRAKIS. Mr. Speaker, I urge everyone to vote to pass this bill so we can quickly make this law and get it to the President.

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

Mr. PALLONE. Mr. Speaker, I also urge support for this 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, S. 164.

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. CLINE. Mr. Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

AMENDING FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO SCOPE OF NEW CHEMICAL EXCLUSIVITY

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (S. 415) to amend the Federal Food, Drug, and Cosmetic Act with respect to the scope of new chemical exclusivity.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 415

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. CLARIFYING THE MEANING OF NEW CHEMICAL ENTITY.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(B) in subsection (j)(5)(F), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(C) in subsection (l)(2)(A)—

(i) by amending clause (i) to read as follows:

''(i) not later than 30 days after the date of approval of such applications—

''(I) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

''(II) for a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; and''; and

(ii) in clause (ii), by inserting ''or biological product'' before the period;

(D) by amending subsection (s) to read as follows:

''(s) REFERRAL TO ADVISORY COMMITTEE.—The Secretary shall—

''(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the approval of such drug or biological if it is—

''(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

''(B) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; or

''(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.''; and

(E) in subsection (u)(1), in the matter preceding subparagraph (A)—

(i) by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(ii) by striking ''same active ingredient'' and inserting ''same active moiety'';

(2) in section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(3) in section 524(a)(4) (21 U.S.C. 360n(a)(4)), by amending subparagraph (C) to read as follows:

''(C) is for—

''(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

''(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.'';

(4) in section 529(a)(4) (21 U.S.C. 360ff(a)(4)), by striking subparagraphs (A) and (B) and inserting the following:

''(A) is for a drug or biological product that is for the prevention or treatment of a rare pediatric disease;

''(B)(i) is for such a drug—

''(I) that contains no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 505; and

''(II) that is the subject of an application submitted under section 505(b)(1); or

''(ii) is for such a biological product—

''(I) that contains no active ingredient that has been previously approved in any other application under section 351(a) or 351(k) of the Public Health Service Act; and

''(II) that is the subject of an application submitted under section 351(a) of the Public Health Service Act;''; and

(5) in section 565A(a)(4) (21 U.S.C. 360bbb–4a(a)(4)), by amending subparagraph (D) to read as follows:

''(D) is for—

''(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

''(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.''.

(b) TECHNICAL CORRECTIONS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by repealing clause (i); and

(B) in subsection (j)(5)(F), by repealing clause (i); and

(2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C. 355a(c)(1)(A)(i)(II)), by striking ''(c)(3)(D)'' and inserting ''(c)(3)(E)''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Florida (Mr. BILIRAKIS) 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 on S. 415.

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, rising prescription drug costs are a concern for so many Americans. Skyrocketing costs can result in some people postponing or altering treatment because the necessary drugs are simply priced out of reach.

One way to help reduce drug costs is to provide early access to generic drugs. This legislation we are considering today will help to do that by ensuring that exclusivity, which can delay generics from entering the market, is only made available to truly innovative products. This will ensure that drug manufacturers cannot game the system by simply making small tweaks to old drugs as a way to block or delay competition. The legislation will also codify the Food and Drug Administration's current approach to awarding exclusivity.

I thank Representatives SCHRADER and GUTHRIE for their bipartisan work on this legislation with Senators CASSIDY, SMITH, and MARSHALL.

Mr. Speaker, I urge my colleagues to support the bill, and I reserve the balance of my time.

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

Mr. Speaker, I rise in support of S. 415, the Ensuring Innovation Act. This legislation is the bipartisan companion to H.R. 1857 led by Representatives GUTHRIE and SCHRADER.

This legislation would ensure that only the most innovative products are eligible for certain market exclusivities and would increase the availability of lower-cost generic drugs. Great work by these Representatives.

Currently, the FDA grants 5 years of marketing exclusivity to drug products determined to be a new chemical entity. Clarifying what qualifies as a new chemical entity will prevent drug manufacturers from receiving exclusivity by making minor changes to existing drugs, which would block generic competition from the market.

This important bipartisan legislation will help lower prescription drug prices while preserving incentives to innovate.

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

Mr. PALLONE. Mr. Speaker, I yield such time as he may consume to the gentleman from Oregon (Mr. SCHRADER), a member of the Energy and Commerce Committee.

Mr. SCHRADER. Mr. Speaker, I rise today to speak in support of S. 415, a bill that has the same policy as my own and Mr. GUTHRIE's here in the House, H.R. 1857, the Protecting Access to Safe and Effective Medicines Act.

This bill is a simple fix, providing clarity around the drug approval process by increasing the specificity of the language companies may use when submitting these complex and often lengthy applications. Simply put, utilizing the term ''active ingredient'' opens the unintended opportunity for pharmaceutical companies to make minor, relatively nonpharmacological changes to the same chemical and prevent generic alternatives from coming to the marketplace. By changing this language, as this bill does, to ''active moiety,'' we will be able to close another loophole that can be exploited by companies to inappropriately obtain exclusivity and hold back competition in the marketplace, the key mechanism for lowering drug prices.

While this is good policy, it is one small piece of the larger drug-pricing conversation that we need to have. It demonstrates, yet again, that the policies to lower drug prices are bipartisan and bicameral. In fact, there are many such policies that did not get done in the last Congress that offer a starting point for a comprehensive approach addressing drug pricing, and now is the time to continue this important work.

I thank my colleagues on both sides of the aisle for the help in supporting this important bill before us today, and I urge its passage.

Mr. BILIRAKIS. Mr. Speaker, I urge my colleagues to pass this great bill. I commend my colleagues for focusing on this particular issue, which is just so important to our constituents. Again, let's pass this bill as soon as possible and get it to the President.

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

Mr. PALLONE. Mr. Speaker, I also urge support for this 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, S. 415.

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

A motion to reconsider was laid on the table.

FRAUD AND SCAM REDUCTION ACT

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1215) to establish an office within the Federal Trade Commission and an outside advisory group to prevent fraud targeting seniors and to direct the Commission to include additional information in an annual report to Congress on fraud targeting seniors, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1215

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Fraud and Scam Reduction Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

TITLE I—PREVENTING CONSUMER SCAMS DIRECTED AT SENIORS

SEC. 101. SHORT TITLE.

This title may be cited as the ''Stop Senior Scams Act''.

SEC. 102. SENIOR SCAMS PREVENTION ADVISORY GROUP.

(a) ESTABLISHMENT.—There is established a Senior Scams Prevention Advisory Group (referred to in this title as the ''Advisory Group'').

(b) MEMBERS.—The Advisory Group shall be composed of stakeholders such as the following individuals or the designees of those individuals:

(1) The Chairman of the Federal Trade Commission.

(2) The Secretary of the Treasury.

(3) The Attorney General.

(4) The Director of the Bureau of Consumer Financial Protection.

(5) Representatives from each of the following sectors, including trade associations, to be selected by the Federal Trade Commission:

(A) Retail.

(B) Gift cards.

(C) Telecommunications.

(D) Wire-transfer services.

(E) Senior peer advocates.

(F) Consumer advocacy organizations with efforts focused on preventing seniors from becoming the victims of scams.

(G) Financial services, including institutions that engage in digital currency.

(H) Prepaid cards.

(6) A member of the Board of Governors of the Federal Reserve System.

(7) A prudential regulator, as defined in section 1002 of the Consumer Financial Protection Act of 2010 (12 U.S.C. 5481).

(8) The Director of the Financial Crimes Enforcement Network.

(9) Any other Federal, State, or local agency, industry representative, consumer advocate, or entity, as determined by the Federal Trade Commission.

(c) NO COMPENSATION FOR MEMBERS.—A member of the Advisory Group shall serve without compensation in addition to any compensation received for the service of the member as an officer or employee of the United States, if applicable.

(d) DUTIES.—

(1) IN GENERAL.—The Advisory Group shall—

(A) collect information on the existence, use, and success of educational materials and programs for retailers, financial services, and wire-transfer companies, which—

(i) may be used as a guide to educate employees on how to identify and prevent scams that affect seniors; and

(ii) include—

(I) useful information for retailers, financial services, and wire transfer companies for the purpose described in clause (i);

(II) training for employees on ways to identify and prevent senior scams;

(III) best practices for keeping employees up to date on current scams;