(2) transmit to Congress an evaluation of such comments, including any recommendations about the types of information that should be added to or removed from the list.

The SPEAKER pro tempore. Pursuant to the rule, the gentlewoman from California (Ms. ESHOO) and the gentleman from Texas (Mr. BURGESS) each will control 20 minutes.

The Chair recognizes the gentlewoman from California.

GENERAL LEAVE

Ms. ESHOO. 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 H.R. 1520.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from California?

There was no objection.

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

Mr. Speaker, I rise in support of H.R. 1520, the Purple Book Continuity Act of 2019. I am proud that my bipartisan legislation is being considered because it makes important updates and improvements to the Food and Drug Administration's Purple Book.

I am also pleased that it is the first drug pricing bill to be considered by the full House this Congress. The legislation makes it easier for manufacturers to research and develop biosimilars, which are essentially generic biological products, and drive down prescription drug prices for the American people.

The so-called ''Purple Book'' lists biological products, including biosimilars, that are licensed by the FDA. The Purple Book is a resource published by the FDA that includes very important information about existing products, about including designations that extend the product's exclusivity, and what active patents each product has.

Today, the FDA is not statutorily required to publish this information, nor is the agency required to update the resource in a timely manner. The Purple Book also is not currently user-friendly and is burdensome for companies to access and use. Companies rely on the Purple Book to inform their research and development activities, and it is imperative that the resource is up-to-date and easily accessible, so they can move quickly to produce cost-saving biosimilar drugs which are, essentially, as I said previously, generic versions of the most complex, high-cost biological products.

The Purple Book Continuity Act builds on previous work to promote the development of biosimilars and other alternatives to the highest-priced biologic products by putting necessary patent information into an easily accessible resource so companies can more efficiently and effectively direct their work to develop biosimilars.

The Purple Book Continuity Act takes an important step to make it easier for the manufacturers to access patent and exclusivity information they need to invest in biosimilar development so that drug prices—the whole point is so that drug prices can be lowered for the American people.

So the Purple Book Continuity Act passed the Energy and Commerce Committee by voice vote last month and, today, I urge my colleagues to support it.

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

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

I rise today in support of H.R. 1520, the Purple Book Continuity Act. This bill has moved through regular order in the Energy and Commerce Committee and does, in fact, have broad bipartisan support. This may be only a small part of solving the problems of drug pricing, however, it is an important part of that question.

Through the Biologics Price Competition and Innovation Act, Congress established a pathway for biosimilars to enter the therapeutic market so that patients would have more treatment options, more access to lifesaving medications, and lower healthcare costs.

As the Food and Drug Administrator, at the time, Scott Gottlieb announced, there is a four-point plan to increase biosimilar availability. The plan would focus on increasing market competition by reducing delays to entry; improving the efficiency of biosimilar development; maximize the clarity of the regulatory process; and develop a communications strategy to promote biosimilars.

The Purple Book plays an important role in biosimilar development. It lists the licensed biologic products, including any biosimilar or interchangeable biologic product, and any relevant exclusivity information. The Purple Book is not currently required by law and takes the form of two separate and sometimes cumbersome PDF files.

H.R. 1520 codifies the Purple Book and requires the Food and Drug Administration to publish the information in a searchable format, similar to the Orange Book. This bill will make the Purple Book a more useful tool for developers of biosimilars, in addition to providers, payors, and patients.

The Food and Drug Administration provided us with some important feedback that would ensure that the agency will be able to effectively implement this legislation should it become law. Enhancing the Purple Book is critical to the transparency of the relevant intellectual property protections, as well as other factors considered by the developers of biosimilars.

So I certainly want to thank the chairwoman for her willingness to work with us and the agency on this important issue. I am pleased to cosponsor this bill, and I urge other Members to support it this afternoon.

Mr. Speaker, I have no other speakers. I urge support of this bill upon passage, and I yield back the balance of my time.

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

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from California (Ms. ESHOO) that the House suspend the rules and pass the bill, H.R. 1520, 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.

Ms. ESHOO. 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, further proceedings on this question will be postponed.

The point of no quorum is considered withdrawn.

ORANGE BOOK TRANSPARENCY ACT OF 2019

Ms. ESHOO. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1503) to amend the Federal Food, Drug, and Cosmetic Act regarding the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1503

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 ''Orange Book Transparency Act of 2019''.

SEC. 2. ORANGE BOOK.

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended to read as follows:

''(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

''(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

''(B) a full list of the articles used as components of such drug;

''(C) a full statement of the composition of such drug;

''(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

''(E) such samples of such drug and of the articles used as components thereof as the Secretary may require;

''(F) specimens of the labeling proposed to be used for such drug;

''(G) any assessments required under section 505B; and

''(H) patent information, with respect to each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, and consistent with the following requirements:

''(i) The applicant shall file with the application the patent number and the expiration date of—

''(I) any patent which claims the drug for which the applicant submitted the application and is a drug substance (including active ingredient) patent or a drug product (including formulation and composition) patent; and

''(II) any patent which claims the method of using such drug.

''(ii) If an application is filed under this subsection for a drug and a patent of the type described in clause (i) which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include such patent information.

Upon approval of the application, the Secretary shall publish the information submitted under subparagraph (H). The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by subparagraph (A).''.

(b) CONFORMING CHANGES TO REQUIREMENTS FOR SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended—

(1) by inserting after ''the patent number and the expiration date of any patent which'' the following: ''fulfills the criteria in subsection (b) and'';

(2) by inserting after the first sentence the following: ''Patent information that is not the type of patent information required by subsection (b) shall not be submitted.''; and

(3) by inserting after ''could not file patent information under subsection (b) because no patent'' the following: ''of the type required to be submitted in subsection (b)''.

(c) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(iv) For each drug included on the list, the Secretary shall specify each exclusivity period that is applicable and has not concluded under—

''(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E) of this section;

''(II) clause (iv) or (v) of paragraph (5)(B) of this subsection;

''(III) clause (ii), (iii), or (iv) of paragraph (5)(F) of this subsection;

''(IV) section 505A;

''(V) section 505E; or

''(VI) section 527(a).''.

(d) REMOVAL OF INVALID PATENTS.—

(1) IN GENERAL.—Section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(D)(i) The holder of an application approved under subsection (c) for a drug on the list shall notify within 14 days the Secretary in writing if either of the following occurs:

''(I) The Patent Trial and Appeals Board issues a decision from which no appeal has been or can be taken that a patent for such drug is invalid.

''(II) A court issues a decision from which no appeal has been or can be taken that a patent for such drug is invalid.

''(ii) The holder of an approved application shall include in any notification under clause (i) a copy of the decision described in subclause (I) or (II) of clause (i).

''(iii) The Secretary shall remove from the list any patent that is determined to be invalid in a decision described in subclause (I) or (II) of clause (i)—

''(I) promptly; but

''(II) not before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV) that such patent was invalid.''.

(2) APPLICABILITY.—Subparagraph (D) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), as added by paragraph (1), applies only with respect to a decision described in such subparagraph that is issued on or after the date of enactment of this Act.

(e) REVIEW AND REPORT.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) solicit public comment regarding the types of patent information that should be included on the list under section 507(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(2) transmit to the Congress an evaluation of such comments, including any recommendations about the types of patent information that should be included on or removed from such list.

SEC. 3. GAO REPORT TO CONGRESS.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Comptroller General of the United States (referred to in this section as the ''Comptroller General'') shall submit to the Committee on Energy and Commerce of the House of Representatives a report on the patents included in the list published under section 505(j)(7) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(7)), including an analysis and evaluation of the types of patents included in such list and the claims such patents make about the products they claim.

(b) CONTENTS.—The Comptroller General shall include in the report under subsection (a)—

(1) data on the number of—

(A) patents included in the list published under paragraph (7) of section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)), that claim the active ingredient or formulation of a drug in combination with a device that is used for delivery of the drug, together comprising the finished dosage form of the drug; and

(B) claims in each patent that claim a device that is used for the delivery of the drug, but do not claim such device in combination with an active ingredient or formulation of a drug;

(2) data on the date of inclusion in the list under paragraph (7) of such section 505(j) for all patents under such list, as compared to patents that claim a method of using the drug in combination with a device;

(3) an analysis regarding the impact of including on the list under paragraph (7) of such section 505(j) certain types of patent information for drug product applicants and approved application holders, including an analysis of whether—

(A) the listing of the patents described in paragraph (1)(A) delayed the market entry of one or more drugs approved under such section 505(j); and

(B) not listing the patents described in paragraph (1)(A) would delay the market entry of one or more such drugs; and

(4) recommendations about which kinds of patents relating to devices described in paragraph (1)(A) should be submitted to the Secretary of Health and Human Services for inclusion on the list under paragraph (7) of such section 505(j) and which patents should not be required to be so submitted.

The SPEAKER pro tempore. Pursuant to the rule, the gentlewoman from California (Ms. ESHOO) and the gentleman from Texas (Mr. BURGESS) each will control 20 minutes.

The Chair recognizes the gentlewoman from California.

GENERAL LEAVE

Ms. ESHOO. 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 H.R. 1503.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from California?

There was no objection.

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

Mr. Speaker, I rise in support of H.R. 1503. This is a different color book. It is the Orange Book Transparency Act of 2019, sponsored by the gentlewoman from Illinois, Congresswoman ROBIN KELLY. Her bipartisan legislation makes important updates to the Food and Drug Administration's Orange Book to ensure that this resource is accurate and up-to-date to promote the development of generic drugs that save so many Americans so much money.

When it passed in 1984, the Drug Price Competition and Patent Term Restoration Act, also referred to as Hatch-Waxman, created the Orange Book as a resource for drug manufacturers to reference when deciding when and how to seek approval for new drug products. The so-called ''Orange Book'' contains valuable information, is regularly referenced by manufacturers, and is published in a user-friendly way on FDA's website.

But this resource has not been updated since it was created in 1994. That is a long time ago. It is over 3 decades ago. And the Orange Book Transparency Act of 2019 makes important updates to the resource to adapt to the changes in drug development since Hatch-Waxman became law.

Generic drug manufacturers rely heavily on the Orange Book, and it is imperative that this resource is accurate and up-to-date so drug manufacturers can invest in products that promote competition and lower drug prices for the American people.

The Orange Book Transparency Act of 2019 passed the Energy and Commerce Committee by voice vote last month, and I was proud to support it. I urge my colleagues to support the Orange Book Transparency Act of 2019 today.

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

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

Mr. Speaker, I rise today in support of H.R. 1503, the Orange Book Transparency Act of 2019. This is a bipartisan product that moved through the Energy and Commerce Committee, and I would like to thank Representative ROBIN KELLY for introducing this legislation.

The publication of the Approved Drug Products with Therapeutic Equivalence Evaluations, known as the Orange Book, lists drug products that have been approved by the Food and Drug Administration on the basis of safety and effectiveness. Importantly, the Orange Book lists therapeutic equivalence evaluations for approved multisource prescription drug products in addition to relevant patent and exclusivity information.

This publication provides information to State health agencies, prescribers, and to others to inform decisionmaking, and allow for the containment of healthcare costs, as well as educate the public.

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A preliminary version of the Orange Book was produced in 1979. It was not until 1984, with the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, that Congress codified the Orange Book.

This bill amends existing statute to make the Orange Book more useful, particularly for manufacturers of generic drugs. Enactment of this bill will allow these manufacturers to know which branded products face competition and when those products will no longer be protected by patents. Insurance companies, doctors, and patients will be able to determine when a generic alternative is available for a more expensive branded product.

The Food and Drug Administration is already performing the practices contained in this bill, but the legislation would codify current practices and ensure that certain patents are listed in the Orange Book. Additionally, patents that are found invalid would have to be removed following the conclusion of any appeals process.

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

Ms. ESHOO. Mr. Speaker, I yield 4 minutes to the gentlewoman from Illinois (Ms. KELLY), the author of H.R. 1503 and a wonderful member of the Health Subcommittee.

Ms. KELLY of Illinois. Mr. Speaker, I am pleased today to speak on my bill, H.R. 1503, the Orange Book Transparency Act, and the critical issue of transparency in the drug and medical device development space.

Should my colleagues vote in favor of this significant bill, the Orange Book Transparency Act will more efficiently achieve lowered costs and higher quality life-saving medicines for consumers. It will enhance market competition by getting generic drugs to market more rapidly. As much data show us, enhancing the market for generic drugs is one of the quickest ways to lower the costs that consumers pay at the pharmacy.

Two things matter to me with respect to healthcare costs. One, we must be proactive in enhancing transparency with regard to the information made available to generic drug developers. Most importantly, we must improve efficiency in the market for prescription drugs in order to ultimately lower costs to patients, their families, and their caregivers.

The Orange Book Transparency Act addresses both of these points by ensuring clarity in patent and exclusivity information maintained by FDA. It also requires that the Government Accountability Office study the effects of listing drug delivery patents in the Orange Book.

To be very clear, I support intellectual property protections for those researching and developing innovative treatments, but we have the responsibility to close loopholes that allow drugmakers to prevent timely access to information that would lead to new generic drug development, increasing patient access and affordability.

Today, I present a strong and straightforward piece of legislation in order to get lower-cost drugs to Americans in my district and across the country. I am ecstatic that this bill is not only straightforward but also bipartisan.

Mr. Speaker, I thank my colleague from Kentucky, Mr. GUTHRIE, for his work on this bill and key stakeholders for their feedback throughout the process.

The Orange Book Transparency Act moves us in the right direction toward transparency and lower drug costs.

Mr. Speaker, I urge all my colleagues to vote in support of H.R. 1503 today.

Mr. BURGESS. Mr. Speaker, I yield 3 minutes to the gentleman from Kentucky (Mr. GUTHRIE), the Republican ranking member of the Oversight and Investigations Subcommittee of the Energy and Commerce Committee.

Mr. GUTHRIE. Mr. Speaker, I rise today in support of H.R. 1503, the Orange Book Transparency Act of 2019.

The Food and Drug Administration's list of approved brand name therapeutic drug products, known as the Orange Book, plays an important role in drug development. H.R. 1503 will ensure the Orange Book continues to be effective and accurate by requiring drug companies to provide up-to-date information on patents that are relevant to each individual drug. It also directs the Government Accountability Office to study the impact of the patents being listed in the Orange Book.

Mr. Speaker, I thank Congresswoman KELLY from Illinois for her commitment to maintaining the value of the Orange Book to drug manufacturers, payers, providers, and patients. I appreciate her willingness to work together in a bipartisan manner, and I urge my colleagues to support H.R. 1503.

Mr. BURGESS. Mr. Speaker, I yield myself the balance of my time.

H.R. 1503 would support the work that the Food and Drug Administration is already conducting and facilitate competition in the marketplace. Therefore, I urge my fellow Members to support this important legislation.

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

Ms. ESHOO. Mr. Speaker, I urge all Members of the House to support this bipartisan legislation that is going to move us closer to our overall goal of lowering the cost of prescription drugs for the American people.

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

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from California (Ms. ESHOO) that the House suspend the rules and pass the bill, H.R. 1503, 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.

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

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this motion will be postponed.

ADVANCING CRITICAL CONNECTIVITY EXPANDS SERVICE, SMALL BUSINESS RESOURCES, OPPORTUNITIES, ACCESS, AND DATA BASED ON ASSESSED NEED AND DEMAND ACT

Mr. TONKO. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1328) to establish the Office of Internet Connectivity and Growth, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1328

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 ''Advancing Critical Connectivity Expands Service, Small Business Resources, Opportunities, Access, and Data Based on Assessed Need and Demand Act'' or the ''ACCESS BROADBAND Act''.

SEC. 2. ESTABLISHMENT OF THE OFFICE OF INTERNET CONNECTIVITY AND GROWTH.

Not later than 180 days after the date of the enactment of this Act, the Assistant Secretary shall establish the Office of Internet Connectivity and Growth within the National Telecommunications and Information Administration.

SEC. 3. DUTIES.

(a) OUTREACH.—The Office shall—

(1) connect with communities that need access to high-speed internet and improved digital inclusion efforts through various forms of outreach and communication techniques;

(2) hold regional workshops across the country to share best practices and effective strategies for promoting broadband access and adoption;

(3) develop targeted broadband training and presentations for various demographic communities through various media; and

(4) develop and distribute publications (including toolkits, primers, manuals, and white papers) providing guidance, strategies, and insights to communities as the communities develop strategies to expand broadband access and adoption.

(b) TRACKING OF FEDERAL DOLLARS.—

(1) BROADBAND INFRASTRUCTURE.—The Office shall track the construction and use of and access to any broadband infrastructure built using any Federal support in a central database.

(2) ACCOUNTING MECHANISM.—The Office shall develop a streamlined accounting mechanism by which any agency offering a Federal broadband support program and the Commission through the Universal Service Fund shall provide the information described in paragraph (1) in a standardized and efficient fashion.

(3) REPORT.—Not later than 1 year after the date of the enactment of this Act, and every year thereafter, the Office shall make public on the website of the Office and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate a report on the following: