

and she has been a tremendous leader in our Lancaster County community. Just last year, the health center that she leads logged over 80,000 patient visits.

Madam Speaker, Dr. Shirk led the health center during a pivotal time in the organization's history. Under her steadfast leadership, she grew the organization in many ways, including doubling the organization's operating budget, increasing its staff by nearly 50 percent, and increasing accessibility at two new sites in Lancaster City.

Dr. Shirk will be retiring later this year. It is a pleasure to honor such an incredible community leader. We thank her for her years of service and wish her well in her retirement.

REMEMBERING ANNE MARIE FEENEY

(Mr. SCHRADER asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. SCHRADER. Mr. Speaker, it is with a heavy heart that I rise today to recognize and remember a dear friend and devoted, lifelong public servant, my former executive assistant Anne Marie Feeney.

Anne Marie began her more than four decades in Congress in the 1970s with Senator Robert Byrd and retired her career in my office in 2014.

Across the Capitol, Anne Marie was a force to be reckoned with, having served through eight Presidencies and more than 20 Congresses. She knew her stuff.

Beginning her career at a time when few women were hired as congressional staff, she spearheaded the charge to bring full-time childcare to Congress for both Members and staff.

When I was first elected to Congress in 2008, it was Anne Marie who helped me set up my office and guided me through the ins and outs of Congress. I credit her with building the close-knit family culture my office is fortunate to have.

My thoughts this past 2 weeks have been with her daughter, Marybeth; son-in-law, Jamie; grandson, Kyle; sister, Mollie; and brother-in-law, John, as we mourn a great loss and remember the incredibly strong and caring woman that was Anne Marie Feeney.

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CREATION OF THE SKYLINE DRUG TASK FORCE

(Mr. RIGGLEMAN asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. RIGGLEMAN. Mr. Speaker, I rise today to talk about an issue of grave concern in my district. The Skyline Drive corridor in central and western Virginia has become the center of a drug trafficking problem that is ravaging my district.

This challenge has warranted the creation of a Skyline Drug Task Force to combat drug problems in the community. This counter-drug team has carried out searches and made arrests, including of an individual suspected to be a high-level member of a Mexican drug trafficking organization, a cartel, who had, according to the judge, caused unfathomable damage to the community.

The damage caused by this organization and the many others trafficking in our communities and in the Fifth District of Virginia is very real and very lasting.

It is necessary, for the safety of my constituents, to have the region designated as a High Intensity Drug Area to give law enforcement the funding and support they need to continue the fight against the dangerous drug dealers.

APPOINTMENT OF MEMBERS TO THE CONGRESSIONAL-EXECUTIVE COMMISSION ON THE PEOPLE'S REPUBLIC OF CHINA

The SPEAKER pro tempore (Mr. COX of California). The Chair announces the Speaker's appointment, pursuant to 22 U.S.C. 6913, and the order of the House of January 3, 2019, of the following Members on the part of the House to the Congressional-Executive Commission on the People's Republic of China:

- Ms. KAPTUR, Ohio
- Mr. SUOZZI, New York
- Mr. MALINOWSKI, New Jersey
- Mr. McADAMS, Utah
- Mr. SMITH, New Jersey
- Mr. MAST, Florida

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or votes objected to under clause 6 of rule XX.

The House will resume proceedings on postponed questions at a later time.

PURPLE BOOK CONTINUITY ACT

Ms. ESHOO. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1520) to amend the Public Health Service Act to provide for the publication of a list of licensed biological products, and for other purposes, as amended.

The Clerk read the title of the bill. The text of the bill is as follows:

H.R. 1520

*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 "Purple Book Continuity Act of 2019".*

SEC. 2. PUBLIC LISTING.

*Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended by adding at the end the following:*

“(9) PUBLIC LISTING.—

“(A) IN GENERAL.—

“(i) INITIAL PUBLICATION.—Not later than 180 days after the date of enactment of the Purple Book Continuity Act of 2019, the Secretary shall publish and make available to the public in a searchable, electronic format—

“(I) a list in alphabetical order of the non-proprietary or proper name of each biological product for which a biologics license under subsection (a) or this subsection is in effect, or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, as of such date of enactment;

“(II) the date of approval of the marketing application and the application number; and

“(III) the marketing or licensure status of the biological product for which a biologics license under subsection (a) or this subsection is in effect or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

“(ii) REVISIONS.—Every 30 days after the publication of the first list under clause (i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period.

“(iii) PATENT INFORMATION.—Not later than 30 days after a list of patents under subsection (1)(3)(A), or a supplement to such list under subsection (1)(7), has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (1)(3)(A) or (1)(7), the reference product sponsor shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.

“(iv) LISTING OF EXCLUSIVITIES.—For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period that is applicable and has not concluded under paragraph (6) or paragraph (7).

“(B) WITHDRAWAL OR SUSPENSION OF LICENSURE.—If the licensing of a biological product was withdrawn or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If the withdrawal or suspension occurred after its publication in such list, the reference product sponsor shall notify the Secretary that—

“(i) the biological product shall be immediately removed from such list—

“(I) for the same period as the withdrawal or suspension; or

“(II) if the biological product has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety, purity, or potency reasons; and

“(ii) a notice of the removal shall be published in the Federal Register.”.

SEC. 3. REVIEW AND REPORT ON TYPES OF INFORMATION TO BE LISTED.

Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) solicit public comment regarding the type of information, if any, that should be added to or removed from the list required by paragraph (9) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as added by section 2; and

(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 devel-

opment 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 co-sponsor 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*