Whereas the Historian and the Clerk of the House of Representatives published a historical record in September 2020 entitled ''`We Are in Earnest for Our Rights': Rainey and the Struggle for Reconstruction'', chronicling the legacy of Representative Joseph Rainey: Now, therefore, be it

Resolved, That room H-150 of the United States Capitol is designated as ''The Joseph H. Rainey Room'' to honor the historic life, career, and legacy of Representative Joseph Rainey of South Carolina on the 150th anniversary of his seating as a member of the House of Representatives.

The resolution was agreed to.

A motion to reconsider was laid on the table.

CORRECTING THE ENROLLMENT OF S. 1869

Mr. BROWN of Maryland. Madam Speaker, I ask unanimous consent to take from the Speaker's table the concurrent resolution (S. Con. Res. 51) correcting the enrollment of S. 1869, and ask for its immediate consideration in the House.

The Clerk read the title of the concurrent resolution.

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

There was no objection.

The text of the concurrent resolution is as follows:

S. CON. RES. 51

Resolved by the Senate (the House of Representatives concurring), That in the enrollment of S. 1869, an Act to require the disclosure of ownership of high-security space leased to accommodate a Federal agency, and for other purposes, the Secretary of the Senate shall, in section 4(c)(3) of the Act, strike ''thereafter for years'' and insert ''thereafter for 9 years''.

The concurrent resolution was concurred in.

A motion to reconsider was laid on the table.

ORANGE BOOK TRANSPARENCY ACT OF 2019

Mrs. DINGELL. Madam Speaker, I ask unanimous consent to take from the Speaker's table 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, with the Senate amendment thereto, and concur in the Senate amendment.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will report the Senate amendment.

The Clerk read as follows:

Senate amendment:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Orange Book Transparency Act of 2020''.

SEC. 2. ORANGE BOOK MODERNIZATION.

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—

(1) IN GENERAL.—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)(A) 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—

''(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

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

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

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

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

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

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

''(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

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

''(II) claims a method of using such drug for which approval is sought or has been granted in the application.

''(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the patent number and expiration date.''.

(b) SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—

(1) IN GENERAL.—Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(2)) is amended—

(A) by inserting before the first sentence the following: ''Not later than 30 days after the date of approval of an application submitted under subsection (b), the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. If a patent described in subsection (b)(1)(A)(viii) is issued after the date of approval of an application submitted under subsection (b), the holder of the approved application shall, not later than 30 days after the date of issuance of the patent, file the patent number and the expiration date of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use has been granted in the application.'';

(B) in the first sentence following the sentences added by subparagraph (A), by striking ''which claims the drug for which'' and all that follows through ''of the drug.'' and inserting ''described in subsection (b)(1)(A)(viii).'';

(C) in the second sentence following the sentences added by subparagraph (A), by inserting after ''could not file patent information under subsection (b) because no patent'' the following: ''of the type for which information is required to be submitted in subsection (b)(1)(A)(viii)''; and

(D) by adding at the end the following: ''Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.''.

(2) UPDATING LIST.—Clause (iii) of section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by striking ''(b) or''.

(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 any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which such period has not yet expired, under—

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

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

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

''(IV) section 505A;

''(V) section 505E;

''(VI) section 527(a); or

''(VII) subsection (u).''.

(d) ORANGE BOOK UPDATES WITH RESPECT TO INVALIDATED PATENTS.—

(1) AMENDMENT.—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) In the case of a listed drug for which the list under subparagraph (A)(i) includes a patent for such drug, and any claim of the patent has been cancelled or invalidated pursuant to a final decision issued by the Patent Trial and Appeal Board of the United States Patent and Trademark Office or by a court, from which no appeal has been, or can be, taken, if the holder of the applicable application approved under subsection (c) determines that a patent for such drug, or any patent information for such drug, no longer meets the listing requirements under this section—

''(i) the holder of such approved application shall notify the Secretary, in writing, within 14 days of such decision of such cancellation or invalidation and request that such patent or patent information, as applicable, be amended or withdrawn in accordance with the decision issued by the Patent Trial and Appeal Board or a court;

''(ii) the holder of such approved application shall include in any notification under clause (i) information related to such patent cancellation or invalidation decision and submit such information, including a copy of such decision, to the Secretary; and

''(iii) the Secretary shall, in response to a notification under clause (i), amend or remove patent or patent information in accordance with the relevant decision from the Patent Trial and Appeals Board or court, as applicable, except that the Secretary shall not remove from the list any patent or patent information 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).''.

(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 1 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, or removed from, 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 Congress a summary of such comments and actions the Food and Drug Administration is considering taking, if any, in response to public comment pursuant to paragraph (1) about the types of patent information that should be included or removed from such list.

(f) GAO REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 2 years 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 Health, Education, Labor, and Pensions of the Senate and 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)) that claim an active ingredient or formulation of a drug in combination with a device that is used for delivery of such drug, including an analysis of such patents and their claims.

(2) CONTENT.—The Comptroller General shall include in the report under paragraph (1)—

(A) data on—

(i) the number of 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)) that claim the active ingredient or formulation of a drug in combination with a device that is used for delivery of the drug, and that together claim the finished dosage form of the drug; and

(ii) the number of claims with respect to each patent included in the list published under such section 505(j)(7) 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;

(B) an analysis of the listing of patents described in subparagraph (A)(ii), including the timing of listing such patents in relation to patents described in subparagraph (A)(i), and the effect listing the patents described in subparagraph (A)(ii) has on market entry of one or more drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act as compared to the effect of not listing the patents described in subparagraph (A)(ii); and

(C) recommendations about which kinds of patents relating to devices described in subparagraph (A)(i) should be submitted to the Secretary of Health and Human Services for inclusion on the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act and which patents should not be required to be so submitted in order to reduce barriers to approval and market entry.

(g) CONFORMING AMENDMENTS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (c)(3)(E), by striking ''clause (A) of subsection (b)(1)'' each place it appears and inserting ''subsection (b)(1)(A)(i)''; and

(2) in subsection (j)(2)(A)(vi), by striking ''clauses (B) through (F) of subsection (b)(1)'' and inserting ''clauses (ii) through (vi) of subsection (b)(1)(A)''.

Mrs. DINGELL (during the reading). Madam Speaker, I ask unanimous consent to dispense with the reading.

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

There was no objection.

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

There was no objection.

A motion to reconsider was laid on the table.

SAFEGUARDING THERAPEUTICS ACT

Mrs. DINGELL. Madam Speaker, I ask unanimous consent to take from the Speaker's table the bill (H.R. 5663) to amend the Federal Food, Drug, and Cosmetic Act to give authority to the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to destroy counterfeit devices, with the Senate amendment thereto, and concur in the Senate amendment.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will report the Senate amendment.

The Clerk read as follows:

Senate amendment:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safeguarding Therapeutics Act''.

SEC. 2. AUTHORITY TO DESTROY COUNTERFEIT DEVICES.

(a) IN GENERAL.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—

(1) in the fourth sentence, by inserting ''or counterfeit device'' after ''counterfeit drug''; and

(2) by striking ''The Secretary of the Treasury shall cause the destruction of'' and all that follows through ''liable for costs pursuant to subsection (c).'' and inserting the following: ''The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug or device refused admission under this section, if such drug or device is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))) and was not brought into compliance as described under subsection (b). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug or device under the seventh sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c).''.

(b) DEFINITION.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended—

(1) by redesignating subparagraphs (1), (2), and (3) as clauses (A), (B), and (C), respectively; and

(2) after making such redesignations—

(A) by striking ''(h) The term'' and inserting ''(h)(1) The term''; and

(B) by adding at the end the following:

''(2) The term 'counterfeit device' means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor.''.

Mrs. DINGELL (during the reading). Madam Speaker, I ask unanimous consent to dispense with the reading of the amendment.

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

There was no objection.

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

There was no objection.

A motion to reconsider was laid on the table.

LIFESPAN RESPITE CARE REAUTHORIZATION ACT OF 2020

Mrs. DINGELL. Madam Speaker, I ask unanimous consent that the Committee on Energy and Commerce be discharged from further consideration of the bill (H.R. 8906) to amend title XXIX of the Public Health Service Act to reauthorize the program under such title relating to lifespan respite care, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

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

There was no objection.

The text of the bill is as follows:

H.R. 8906

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 ''Lifespan Respite Care Reauthorization Act of 2020''.

SEC. 2. REAUTHORIZATION OF LIFESPAN RESPITE CARE PROGRAM.

(a) DATA COLLECTION AND REPORTING.—Section 2904 of the Public Health Service Act (42 U.S.C. 300ii–3) is amended to read as follows:

''SEC. 2904. DATA COLLECTION AND REPORTING.

''(a) IN GENERAL.—Each State agency awarded a grant or cooperative agreement under section 2902 shall report such data, information, and metrics as the Secretary may require for purposes of—

''(1) evaluating State programs and activities funded pursuant to such grant or cooperative agreement, including any results pursuant to section 2902(d)(2)(B)(xii); and

''(2) identifying effective programs and activities funded pursuant to section 2902.

''(b) REPORT.—Not later than October 1, 2023, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the outcomes of the programs and activities funded pursuant to section 2902, including any effective programs and activities identified.''.

(b) FUNDING.—Section 2905 of the Public Health Service Act (42 U.S.C. 300ii–4) is amended by striking ''title'' and all that follows through the period and inserting ''title, $10,000,000 for each of fiscal years 2020 through fiscal year 2024.''.

The bill was ordered to be engrossed and read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.