

fiscal responsibility, and his work on farm policy: Now, therefore, be it

Resolved, That—

(1) the Senate has heard with profound sorrow and deep regret the announcement of the death of the Honorable Roger William Jepsen, former member of the United States Senate from the State of Iowa;

(2) the Senate respectfully requests that the Secretary of the Senate—

(A) communicate this resolution to the House of Representatives; and

(B) transmit an enrolled copy of this resolution to the family of the Honorable Roger William Jepsen; and

(3) when the Senate adjourns today, it stand adjourned as a further mark of respect to the memory of the Honorable Roger William Jepsen.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2692. Mr. MARKEY submitted an amendment intended to be proposed by him to the bill S. 2054, to posthumously award the Congressional Gold Medal, collectively, to Glen Doherty, Tyrone Woods, J. Christopher Stevens, and Sean Smith, in recognition of their contributions to the Nation; which was referred to the Committee on Banking, Housing, and Urban Affairs.

SA 2693. Mr. MCCONNELL (for Mr. ALEXANDER) proposed an amendment to 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.

TEXT OF AMENDMENTS

SA 2692. Mr. MARKEY submitted an amendment intended to be proposed by him to the bill S. 2054, to posthumously award the Congressional Gold Medal, collectively, to Glen Doherty, Tyrone Woods, J. Christopher Stevens, and Sean Smith, in recognition of their contributions to the Nation; which was referred to the Committee on Banking, Housing, and Urban Affairs; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. FINDINGS.

Congress makes the following findings:

(1) On September 11, 2012, the United States consulate, and its personnel in Benghazi, Libya, were attacked by militants.

(2) Four Americans were killed in the attack, including Ambassador J. Christopher Stevens, Sean Smith, Glen Doherty, and Tyrone Woods.

(3) Glen Doherty and Tyrone Woods were former Navy SEALs who served as security personnel in Libya. As the attack unfolded, they bravely attempted to defend American property and protect United States diplomatic personnel. In so doing, they selflessly sacrificed their own lives.

(4) Glen Doherty was a Navy SEAL for 12 years and served in Iraq and Afghanistan. He attained the rank of Petty Officer First Class and earned the Navy and Marine Corps Commendation Medal. After leaving the Navy, Glen Doherty worked with the Department of State to protect American diplomats.

(5) Tyrone Woods served for 20 years as a Navy SEAL including tours in Iraq and Afghanistan. In Iraq he led multiple raids and reconnaissance missions and earned the Bronze Star. After retiring from the Navy as a Senior Chief Petty Officer, Tyrone Woods worked with the Department of State to protect American diplomats.

(6) J. Christopher Stevens served for 21 years in the U.S. Foreign Service. He was serving as U.S. Ambassador to Libya and previously served twice in the country, as both Special Representative to the Libyan Transitional National Council and as the Deputy Chief of Mission. Earlier in his life, he also served as a Peace Corps volunteer teaching English in Morocco.

(7) Sean Smith served for 6 years in the U.S. Air Force. He attained the rank of Staff Sergeant and was awarded the Air Force Commendation Medal. After leaving the Air Force, Sean Smith served for 10 years in the State Department on various assignments, which took him to places such as Baghdad, Brussels, Pretoria, and The Hague.

(8) As their careers attest, all four men served their country honorably.

SEC. 2. CONGRESSIONAL GOLD MEDAL.

(a) AWARD AUTHORIZED.—The Speaker of the House of Representatives and the President pro tempore of the Senate shall make appropriate arrangements for the posthumous award, on behalf of the Congress, of a single gold medal of appropriate design collectively in commemoration of Glen Doherty, Tyrone Woods, J. Christopher Stevens, and Sean Smith, in recognition of their contributions to the Nation.

(b) DESIGN AND STRIKING.—For the purposes of the award referred to in subsection (a), the Secretary of the Treasury (hereafter in this Act referred to as the “Secretary”) shall strike the gold medal with suitable emblems, devices, and inscriptions, to be determined by the Secretary.

(c) CENTRAL INTELLIGENCE AGENCY MUSEUM.—

(1) IN GENERAL.—Following the award of the gold medal under subsection (a), the gold medal shall be given to the Central Intelligence Agency Museum, where it will be displayed as appropriate and made available for research.

(2) SENSE OF CONGRESS.—It is the sense of Congress that the Central Intelligence Agency Museum should make the gold medal received under paragraph (1) available for display elsewhere, particularly at other appropriate locations associated with Glen Doherty, Tyrone Woods, J. Christopher Stevens, and Sean Smith.

SEC. 3. DUPLICATE MEDALS.

Under such regulations as the Secretary may prescribe, the Secretary may strike and sell duplicates in bronze of the gold medal struck under section 2, at a price sufficient to cover the costs of the medals, including labor, materials, dies, use of machinery, and overhead expenses.

SEC. 4. NATIONAL MEDALS.

Medals struck pursuant to this Act are national medals for purposes of chapter 51 of title 31, United States Code.

SA 2693. Mr. MCCONNELL (for Mr. ALEXANDER) proposed an amendment to 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 follows:

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).”;

(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)”.

PRIVILEGES OF THE FLOOR

Mr. HAWLEY. Mr. President, in recognition of his outstanding service to my office this last year, I ask unanimous consent that Captain Ryan Albin, the defense fellow in my office, be granted floor privileges for the remainder of this Congress.

The PRESIDING OFFICER. Without objection, it is so ordered.

RELATING TO THE DEATH OF THE HONORABLE ROGER WILLIAM JEPSEN, FORMER UNITED STATES SENATOR FOR THE STATE OF IOWA

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 795, submitted earlier today.

The PRESIDING OFFICER. The clerk will report the resolution by title.

The senior assistant legislative clerk read as follows:

A resolution (S. Res. 795) relating to the death of the Honorable Roger William Jepsen, former United States Senator for the State of Iowa.

There being no objection, the Senate proceeded to consider the resolution.

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, and the motions to reconsider be considered made and laid upon the table with no intervening action or debate.

The PRESIDING OFFICER. Without objection, it is so ordered.

The resolution (S. Res. 795) was agreed to.

The preamble was agreed to.

(The resolution, with its preamble, is printed in today's RECORD under “Submitted Resolutions.”)

DHS OPIOID DETECTION RESILIENCE ACT OF 2019

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 502, H.R. 4761.

The PRESIDING OFFICER. The clerk will report the bill by title.

The senior assistant legislative clerk read as follows:

A bill (H.R. 4761) to ensure U.S. Customs and Border Protection officers, agents, and other personnel have adequate synthetic opioid detection equipment, that the Department of Homeland Security has a process to update synthetic opioid detection capability, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. MCCONNELL. I ask unanimous consent that the bill be considered read a third time and passed and the motion to reconsider be considered made and laid upon the table.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (H.R. 4761) was ordered to a third reading, was read the third time, and passed.

SECURING AMERICA'S PORTS ACT

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 530, H.R. 5273.

The PRESIDING OFFICER. The clerk will report the bill by title.

The senior assistant legislative clerk read as follows:

A bill (H.R. 5273) to require the Secretary of Homeland Security to develop a plan to