(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of such cancellation or invalidation and request that such patent or patent information, as applicable, be amended or withdrawn in accordance with the decision issued by the Patent Trial and Appeal Board or a court;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

increase to 100 percent the rates of scanning of commercial and passenger vehicles entering the United States at land ports of entry along the border using large-scale non-intrusive inspection systems to enhance border security, and for other purposes.

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Homeland Security and Governmental Affairs, with an amendment to strike all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Securing America's Ports Act''.

SEC. 2. LARGE-SCALE NON-INTRUSIVE INSPECTION SCANNING PLAN.

(a) DEFINITIONS.—In this section:

(1) LARGE-SCALE NON-INTRUSIVE INSPECTION SYSTEM.—The term ''large-scale, non-intrusive inspection system'' means a technology, including x-ray, gamma-ray, and passive imaging systems, capable of producing an image of the contents of a commercial or passenger vehicle or freight rail car in 1 pass of such vehicle or car.

(2) SCANNING.—The term ''scanning'' means utilizing nonintrusive imaging equipment, radiation detection equipment, or both, to capture data, including images of a commercial or passenger vehicle or freight rail car.

(b) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Homeland Security shall submit a plan to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Homeland Security of the House of Representatives for increasing to 100 percent the rate of high-throughput scanning of commercial and passenger vehicles and freight rail traffic entering the United States at land ports of entry and rail-border crossings along the border using large-scale non-intrusive inspection systems or similar technology to enhance border security.

(c) BASELINE INFORMATION.—The plan under subsection (b) shall include, at a minimum, the following information regarding large-scale non-intrusive inspection systems or similar technology operated by U.S. Customs and Border Protection at land ports of entry and rail-border crossings as of the date of the enactment of this Act:

(1) An inventory of large-scale non-intrusive inspection systems or similar technology in use at each land port of entry.

(2) For each system or technology identified in the inventory under paragraph (1)—

(A) the scanning method of such system or technology;

(B) the location of such system or technology at each land port of entry that specifies whether in use in pre-primary, primary, or secondary inspection area, or some combination of such areas;

(C) the percentage of commercial and passenger vehicles and freight rail traffic scanned by such system or technology;

(D) seizure data directly attributed to scanned commercial and passenger vehicles and freight rail traffic; and

(E) the number of personnel required to operate each system or technology.

(3) Information regarding the continued use of other technology and tactics used for scanning, such as canines and human intelligence in conjunction with large scale, nonintrusive inspection systems.

(d) ELEMENTS.—The plan under subsection (b) shall include the following information:

(1) Benchmarks for achieving incremental progress towards 100 percent high-throughput scanning within the next 6 years of commercial and passenger vehicles and freight rail traffic entering the United States at land ports of entry and rail-border crossings along the border with corresponding projected incremental improvements in scanning rates by fiscal year and rationales for the specified timeframes for each land port of entry.

(2) Estimated costs, together with an acquisition plan, for achieving the 100 percent high-throughput scanning rate within the timeframes specified in paragraph (1), including acquisition, operations, and maintenance costs for large-scale, nonintrusive inspection systems or similar technology, and associated costs for any necessary infrastructure enhancements or configuration changes at each port of entry. Such acquisition plan shall promote, to the extent practicable, opportunities for entities that qualify as small business concerns (as defined under section 3(a) of the Small Business Act (15 U.S.C. 632(a)).

(3) Any projected impacts, as identified by the Commissioner of U.S. Customs and Border Protection, on the total number of commercial and passenger vehicles and freight rail traffic entering at land ports of entry and rail-border crossings where such systems are in use, and average wait times at peak and non-peak travel times, by lane type if applicable, as scanning rates are increased.

(4) Any projected impacts, as identified by the Commissioner of U.S. Customs and Border Protection, on land ports of entry and rail-border crossings border security operations as a result of implementation actions, including any changes to the number of U.S. Customs and Border Protection officers or their duties and assignments.

(e) ANNUAL REPORT.—Not later than 1 year after the submission of the plan under subsection (b), and biennially thereafter for the following 6 years, the Secretary of Homeland Security shall submit a report to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Homeland Security of the House of Representatives that describes the progress implementing the plan and includes—

(1) an inventory of large-scale, nonintrusive inspection systems or similar technology operated by U.S. Customs and Border Protection at each land port of entry;

(2) for each system or technology identified in the inventory required under paragraph (1)—

(A) the scanning method of such system or technology;

(B) the location of such system or technology at each land port of entry that specifies whether in use in pre-primary, primary, or secondary inspection area, or some combination of such areas;

(C) the percentage of commercial and passenger vehicles and freight rail traffic scanned by such system or technology; and

(D) seizure data directly attributed to scanned commercial and passenger vehicles and freight rail traffic;

(3) the total number of commercial and passenger vehicles and freight rail traffic entering at each land port of entry at which each system or technology is in use, and information on average wait times at peak and non-peak travel times, by lane type if applicable;

(4) a description of the progress towards reaching the benchmarks referred to in subsection (d)(1), and an explanation if any of such benchmarks are not achieved as planned;

(5) a comparison of actual costs (including information on any awards of associated contracts) to estimated costs set forth in subsection (d)(2);

(6) any realized impacts, as identified by the Commissioner of U.S. Customs and Border Protection, on land ports of entry and rail-border crossings operations as a result of implementation actions, including any changes to the number of U.S. Customs and Border Protection officers or their duties and assignments;

(7) any proposed changes to the plan and an explanation for such changes, including changes made in response to any Department of Homeland Security research and development findings or changes in terrorist or transnational criminal organizations tactics, techniques, or procedures; and

(8) any challenges to implementing the plan or meeting the benchmarks, and plans to mitigate any such challenges.

Mr. MCCONNELL. I ask unanimous consent that the committee-reported substitute amendment be agreed to; that the bill, as amended, be considered read a third time and passed; and that the amendment to the title be agreed to; and the motion to reconsider be considered made and laid upon the table.

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

The committee-reported amendment in the nature of a substitute was agreed to.

The amendment was ordered to be engrossed and the bill to be read a third time.

The bill was read the third time.

The bill (H.R. 5273), as amended, was passed.

The committee-reported amendment to the title was agreed to, as follows:

Amend the title so as to read: ''An Act to require the Secretary of Homeland Security to develop a plan to increase to 100 percent the rates of scanning of commercial and passenger vehicles and freight rail entering the United States at land ports of entry along the border using large-scale, nonintrusive inspection systems to enhance border security, and for other purposes.''.

ORANGE BOOK TRANSPARENCY ACT OF 2019

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be discharged from further consideration of H.R. 1503 and the Senate proceed to its immediate consideration.

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

The clerk will read the bill by title.

A 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.

There being no objection, the committee was discharged and the Senate proceeded to consider the bill.

Mr. MCCONNELL. I ask unanimous consent that the Alexander substitute amendment at the desk be agreed to; the bill, as amended, 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 amendment (No. 2693), in the nature of a substitute, was agreed to.

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

The amendment was ordered to be engrossed and the bill to be read a third time.

The bill was read the third time.

The bill (H.R. 1503), as amended, was passed.