

identified under clause (ii)(II) as a person authorized to conduct such inspections of device establishments.”; and

(III) in subclause (II), by inserting “or by a person accredited under paragraph (2)” after “by the Secretary”;

(iv) in clause (iv)(I)—

(I) in the first sentence—

(aa) by striking “the two immediately preceding inspections of the establishment” and inserting “inspections of the establishment during the previous 4 years”; and

(bb) by inserting “section” after “pursuant to”;

(II) in the third sentence—

(aa) by striking “the petition states a commercial reason for the waiver”; and

(bb) by inserting “not” after “the Secretary has not determined that the public health would”; and

(III) in the fourth sentence, by striking “granted until” and inserting “granted or deemed to be granted until”; and

(v) in clause (iv)(II)—

(I) by inserting “of a device establishment required to register” after “to be conducted”; and

(II) by inserting “section” after “pursuant to”;

(D) in paragraph (6)(B)(iii)—

(i) in the first sentence, by striking “, and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502 and other” and inserting “and with other”; and

(ii) in the second sentence—

(I) by striking “inspections” and inserting “inspectional findings”; and

(II) by inserting “relevant” after “together with all other”;

(E) in paragraph (6)(B)(iv)—

(i) by inserting “(I)” after “(iv)”; and

(ii) by adding at the end the following:

“(II) If, during the two-year period following clearance under subparagraph (A), the Secretary determines that the device establishment is substantially not in compliance with this Act, the Secretary may, after notice and a written response, notify the establishment that the eligibility of the establishment for the inspections by accredited persons has been suspended.”;

(F) in paragraph (6)(C)(ii), by striking “in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable”;

(G) in paragraph (10)(B)(iii), by striking “a reporting” and inserting “a report”; and

(H) in paragraph (12)—

(i) by striking subparagraph (A) and inserting the following:

“(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);”;

(ii) in subparagraph (E), by striking “obtained by the Secretary” and all that follows and inserting “obtained by the Secretary pursuant to inspections conducted by Federal employees”;

(2) OTHER CORRECTIONS.—

(A) PROHIBITED ACTS.—Section 301(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(gg)), as amended by section 201(d) of Public Law 107-250 (116 Stat. 1609), is amended to read as follows:

“(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.”.

(B) ELECTRONIC LABELING.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), as amended by section 206 of Public Law 107-250 (116 Stat. 1613), is amended, in the last sentence—

(i) by inserting “or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments” after “in health care facilities”;

(ii) by inserting a comma after “means”;

(iii) by striking “requirements of law and, that” and inserting “requirements of law, and that”;

(iv) by striking “the manufacturer affords health care facilities the opportunity” and inserting “the manufacturer affords such users the opportunity”; and

(v) by striking “the health care facility”.

(c) TITLE III; ADDITIONAL AMENDMENTS.—

(1) EFFECTIVE DATE.—Section 301(b) of Public Law 107-250 (116 Stat. 1616), is amended by striking “18 months” and inserting “36 months”.

(2) PREMARKET NOTIFICATION.—Section 510(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(o)), as added by section 302(b) of Public Law 107-250 (116 Stat. 1616), is amended—

(A) in paragraph (1)(B), by striking “, adulterated” and inserting “or adulterated”; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking “, adulterated” and inserting “or adulterated”; and

(ii) in subparagraph (E), by striking “semicritical” and inserting “semi-critical”.

(d) MISCELLANEOUS CORRECTIONS.—

(1) CERTAIN AMENDMENTS TO SECTION 515.—

(A) IN GENERAL.—

(i) TECHNICAL CORRECTION.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)), as amended by sections 209 and 302(c)(2)(A) of Public Law 107-250 (116 Stat. 1613, 1618), is amended by redesignating paragraph (3) (as added by section 209 of such Public Law) as paragraph (4).

(ii) MODULAR REVIEW.—Section 515(c)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(4)(B)) is amended by striking “unless an issue of safety” and inserting “unless a significant issue of safety”.

(B) CONFORMING AMENDMENT.—Section 210 of Public Law 107-250 (116 Stat. 1614) is amended by striking “, as amended” and all that follows through “by adding” and inserting “is amended in paragraph (3), as redesignated by section 302(c)(2)(A) of this Act, by adding”.

(2) CERTAIN AMENDMENTS TO SECTION 738.—

(A) IN GENERAL.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)), as amended by subsection (a), is amended—

(i) in the matter preceding paragraph (1)—

(I) by striking “(a) TYPES OF FEES.—Beginning on” and inserting the following:

“(a) TYPES OF FEES.—

“(1) IN GENERAL.—Beginning on”; and

(II) by striking “this section as follows:” and inserting “this section.”; and

(ii) by striking “(1) PREMARKET APPLICATION,” and inserting the following: “(2) PREMARKET APPLICATION,”.

(B) CONFORMING AMENDMENTS.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j), as amended by subparagraph (A), is amended—

(i) in subsection (d)(1), in the last sentence, by striking “subsection (a)(1)(A)” and inserting “subsection (a)(2)(A)”;

(ii) in subsection (e)(1), by striking “subsection (a)(1)(A)(vii)” and inserting “subsection (a)(2)(A)(vii)”;

(iii) in subsection (e)(2)(C)—

(I) in each of clauses (i) and (ii), by striking “subsection (a)(1)(A)(vii)” and inserting “subsection (a)(2)(A)(vii)”;

(II) in clause (ii), by striking “subsection (a)(1)(A)(i)” and inserting “subsection (a)(2)(A)(i)”;

(iv) in subsection (j), by striking “subsection (a)(1)(D),” and inserting “subsection (a)(2)(D),”.

(C) ADDITIONAL CONFORMING AMENDMENT.—Section 102(b)(1) of Public Law 107-250 (116

Stat. 1600) is amended, in the matter preceding subparagraph (A), by striking “section 738(a)(1)(A)(ii)” and inserting “section 738(a)(2)(A)(ii)”.

(3) PUBLIC LAW 107-250.—Public Law 107-250 is amended—

(A) in section 102(a) (116 Stat. 1589), by striking “(21 U.S.C. 379f et seq.)” and inserting “(21 U.S.C. 379f et seq.)”;

(B) in section 102(b) (116 Stat. 1600)—

(i) by striking paragraph (2);

(ii) in paragraph (1), by redesignating subparagraphs (A) and (B) as paragraphs (1) and (2), respectively; and

(iii) by striking:

“(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—

“(1) IN GENERAL.—A person submitting a premarket report” and inserting:

“(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—A person submitting a premarket report”; and

(C) in section 212(b)(2) (116 Stat. 1614), by striking “, such as phase IV trials.”.

### SEC. 3. REPORT ON BARRIERS TO AVAILABILITY OF DEVICES INTENDED FOR CHILDREN.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services 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 barriers to the availability of devices intended for the treatment or diagnosis of diseases and conditions that affect children. The report shall include any recommendations of the Secretary of Health and Human Services for changes to existing statutory authority, regulations, or agency policy or practice to encourage the invention and development of such devices.

Mr. FRIST. I ask unanimous consent that the Senate concur in the House amendment, the motion to reconsider be laid upon the table, and any statements relating to the bill be printed in the RECORD.

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

### WILKIE D. FERGUSON, JR. UNITED STATES COURTHOUSE

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of S. 1904.

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

The legislative clerk read as follows:

A bill (S. 1904) to designate the United States courthouse located at 400 North Miami Avenue in Miami, Florida as the “Wilkie D. Ferguson, Jr. United States Courthouse”.

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

Mr. FRIST. Mr. President, I ask unanimous consent that the bill be read a third time and passed, the motion to reconsider be laid upon the table, and any statements relating to the bill be printed in the RECORD.

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

The bill (S. 1904) was read the third time and passed, as follows:

S. 1904

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

### SECTION 1. DESIGNATION.

The United States courthouse located at 400 North Miami Avenue in Miami, Florida,

shall be known and designated as the "Wilkie D. Ferguson, Jr. United States Courthouse".

#### SEC. 2. REFERENCES.

Any reference in a law, map, regulation, document, paper, or other record of the United States to the United States courthouse referred to in section 1 shall be deemed to be a reference to the "Wilkie D. Ferguson, Jr. United States Courthouse".

#### SENATOR PAUL SIMON FEDERAL BUILDING

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of S. 2022.

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

The legislative clerk read as follows:

A bill (S. 2022) to designate the Federal building located at 250 West Cherry Street in Carbondale, IL, as the "Senator Paul Simon Federal Building."

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

Mr. DURBIN. Mr. President, on December 9, 2003, we lost our colleague, U.S. Senator Paul Simon, a great public servant and a great friend.

At the age of 19, Paul Simon became the nation's youngest editor-publisher when he accepted a Lion's Club challenge to save the Troy Tribune in Troy, IL. From that start, he built a chain of 13 newspapers in southern and central Illinois. He also used his post in the newspaper world to expose criminal activities and in 1951, at age 22, he was called as a key witness to testify before the U.S. Senate's Crime Investigating Committee.

Paul Simon served the state of Illinois and the United States for decades. He is the only individual to have served in both the Illinois House of Representatives and the Illinois Senate, and the U.S. House of Representatives and U.S. Senate. He served in the state legislature for 14 years, and won the Independent Voters of Illinois' "Best Legislator Award" every session. He also served as Lieutenant Governor for Illinois from 1968 to 1972. In addition, he served in the U.S. Army from 1951 to 1953.

Paul Simon highly valued education and the youth of our nation. In addition to his work in Congress to strengthen public education in America, he started the public affairs reporting program at Sangamon State University, now the University of Illinois at Springfield. He later became the founder and director of the Public Policy Institute at Southern Illinois University in Carbondale, IL, and taught there for more than 6 years. In addition, Paul Simon wrote 22 books and earned over 55 honorary degrees.

From journalism to government to education, Paul Simon set the standard for honesty and caring in public life. He was an unapologetic champion of the less fortunate. He was genuine in his politics, life and values.

Now those of us who loved and respected him will do our best to carry

on his tradition. We will find many ways, great and small, to honor him.

Today, the Senate will pass companion legislation to a bill Congressman JERRY COSTELLO has introduced in the House. This legislation would designate the federal building at 250 West Cherry Street in Carbondale, Illinois as the "Senator Paul Simon Federal Building." I am happy to have Senator FITZGERALD as a cosponsor of this legislation. I thank Senators INHOFE and JEFFORDS for their timely consideration of this legislation in the Senate Environment and Public Works Committee.

Paul Simon moved to Carbondale in 1974, where he was elected to serve in the U.S. House of Representatives. He continued to call the Carbondale area his home until his death. Naming this building in Carbondale after him will help present and future generations remember and honor Paul Simon, a great man who lived in and worked for the people of Carbondale, Illinois and our Nation with the greatest integrity.

Mr. FRIST. Mr. President, I ask unanimous consent that the bill be read the third time and passed, the motion to reconsider be laid upon the table, and that any statements related thereto be printed in the RECORD.

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

The bill (S. 2022) was read the third time and passed, as follows:

S. 2022

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. DESIGNATION OF FEDERAL BUILDING.

The Federal building located at 250 West Cherry Street in Carbondale, Illinois shall be known and designated as the "Senator Paul Simon Federal Building".

#### SEC. 2. REFERENCE.

Any reference in a law, map, regulation, document, paper or other record of the United States to the Federal building referred to in section 1 shall be deemed to be a reference to the Senator Paul Simon Federal Building.

#### RONALD REAGAN FEDERAL BUILDING

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of S. 2043.

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

A bill (S. 2043) to designate a Federal building in Harrisburg, Pennsylvania, as the "Ronald Reagan Federal Building."

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

Mr. FRIST. Mr. President, I ask unanimous consent that the bill be read the third time and passed, the motion to reconsider be laid upon the table, and that any statements relating thereto be printed in the RECORD.

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

The bill (S. 2043) was read the third time and passed, as follows:

S. 2043

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. RONALD REAGAN FEDERAL BUILDING.

(a) DESIGNATION.—The Federal building located at 228 Walnut Street, Harrisburg, Pennsylvania, shall be known and designated as the "Ronald Reagan Federal Building".

(b) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the building referred to in subsection (a) shall be deemed to be a reference to the Ronald Reagan Federal Building.

#### HONORING THE COUNTY OF CUMBERLAND, NC, FOR ITS 250TH ANNIVERSARY

Mr. FRIST. Mr. President, I ask unanimous consent that the Judiciary Committee be discharged from further consideration of S. Res. 307, and the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will state the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 307) honoring the county of Cumberland, North Carolina, its municipalities and community partners as they celebrate the 250th year of the existence of Cumberland County.

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

AMENDMENT NO. 2857

Mr. FRIST. Mr. President, I understand that Senator EDWARDS has an amendment at the desk. I ask unanimous consent that it be considered agreed to, the resolution, as amended, be agreed to, the preamble be agreed to, the motion to reconsider be laid upon the table, and that any statements relating thereto be printed in the RECORD as if read, without intervening action or debate.

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

The amendment (No. 2857) was agreed to, as follows:

Strike all after the resolved clause and insert the following:

That the Senate commemorates the 250th Anniversary Celebration of the county of Cumberland, North Carolina, its municipalities, and other community partners.

The resolution (S. Res. 307), as amended, was agreed to.

The preamble was agreed to.

The resolution, as amended, with its preamble, reads as follows:

S. RES. 307

Whereas for thousands of years before the European settlers arrived, Cumberland County's streams and forests were home to native peoples who lived in the area, hunted, farmed, and buried their dead;

Whereas Cumberland County, located at the head of navigation on the Cape Fear River, quickly became a strong area of trade between the port city of Wilmington and the lower Cape Fear River to the southeast and the Carolina back country to the west;

Whereas the upper Cape Fear Valley in present Cumberland County experienced an early migration of Highland Scots beginning in 1739, many of whom settled in the area