

Whereas on average—

- (1) 36 percent of Ranger School students fail the course during the first four days after the date on which the course begins; and
- (2) only approximately 45 percent of Ranger School students ultimately graduate from the course;

Whereas the Army Reserve is—

- (1) a highly trained force that comprises approximately 20 percent of the total Army; and
- (2) always available to meet the needs of the Army and Joint Force;

Whereas on August 21, 2015, Army Captain Kristen Griest and First Lieutenant Shaye Haver became the first two women to graduate from Ranger School;

Whereas on October 16, 2015, Major Lisa Jaster became the third woman, and the first Army Reserve woman and mother, to graduate from Ranger School and earn the distinctive black and gold Ranger tab;

Whereas Major Lisa Jaster overcame the extreme fatigue, hunger, and stress involved in Ranger training in order to graduate from Ranger School; and

Whereas Major Lisa Jaster has—

- (1) dedicated her life to serving and protecting the United States;
- (2) deployed to both Iraq and Afghanistan; and
- (3) earned the Bronze Star and the Combat Action Badge; Now, therefore, be it

*Resolved*, That the Senate—

(1) honors Major Lisa Jaster for the accomplishment of becoming the first Army Reserve woman and first mother to graduate from Ranger School;

(2) commends the groundbreaking achievements of the first three women to graduate from Ranger School—

- (A) Captain Kristen Griest;
- (B) First Lieutenant Shaye Haver; and
- (C) Major Lisa Jaster;

(3) recognizes the vital role that the Army Reserve plays in protecting and defending the United States; and

(4) celebrates the determination, patriotism, and willingness to lead of all Ranger School graduates.

**SENATE RESOLUTION 297—CONGRATULATING THE MINNESOTA LYNX ON THEIR VICTORY IN THE 2015 WOMEN'S NATIONAL BASKETBALL ASSOCIATION FINALS**

Ms. KLOBUCHAR (for herself and Mr. FRANKEN) submitted the following resolution; which was considered and agreed to:

S. RES. 297

Whereas, on October 14, 2015, the Minnesota Lynx won the 2015 Women's National Basketball Association (commonly known as the "WNBA") championship by beating the Indiana Fever 69 to 52 in game 5 at home in Minneapolis;

Whereas this is the third WNBA championship for the Minnesota Lynx in 5 years;

Whereas the Minnesota Lynx have competed in 4 out of the last 5 WNBA Finals;

Whereas the Minnesota Lynx finished the 2015 season with an impressive 22 wins;

Whereas the Minnesota Lynx beat the Los Angeles Sparks in the Western Conference Semifinals, swept the Phoenix Mercury in the Western Conference Finals, and decisively beat the Indiana Fever in the fifth game of the WNBA Finals;

Whereas a franchise record 18,933 fans attended the clinching game at the Target Center in Minneapolis to cheer on the Minnesota Lynx;

Whereas the Minnesota Lynx—

(1) benefit from stellar leadership from Head Coach Cheryl Reeve and Assistant Coaches Jim Petersen and Shelley Patterson;

(2) feature 5 gold medal-winning athletes, Lindsey Whalen, Maya Moore, Seimone Augustus, Asjha Jones, and Sylvia Fowles, the Finals MVP; and

(3) have on the roster highly talented professionals, including Rebekkah Brunson, Renee Montgomery, Anna Cruz, Shae Kelley, Tricia Liston, Kalana Greene, and Devereaux Peters;

Whereas the Minnesota Lynx are 1 of only 4 WNBA teams to win 3 or more WNBA championships; and

Whereas all 3 of the WNBA championships won by the Lynx have come under the coaching of Cheryl Reeve: Now, therefore, be it

*Resolved*, That the Senate recognizes—

(1) the achievements of the players, coaches, fans, and staff whose dedication helped the Minnesota Lynx win the 2015 WNBA championship; and

(2) the Twin Cities area and the State of Minnesota for enthusiastically supporting women's professional basketball.

**SENATE RESOLUTION 298—RECOGNIZING CONNECTICUT'S SUBMARINE CENTURY, THE 100TH ANNIVERSARY OF THE ESTABLISHMENT OF NAVAL SUBMARINE BASE NEW LONDON, AND CONNECTICUT'S HISTORIC ROLE IN SUPPORTING THE UNDERSEA CAPABILITIES OF THE UNITED STATES**

Mr. BLUMENTHAL (for himself and Mr. MURPHY) submitted the following resolution; which was referred to the Committee on Armed Services:

S. RES. 298

Whereas, on March 2, 1867, Congress enacted a naval appropriations Act that authorized the Secretary of the Navy to "receive and accept a deed of gift, when offered by the State of Connecticut, of a tract of land with not less than one mile of shore front on the Thames River near New London, Connecticut, to be held by the United States for naval purposes";

Whereas the people of Connecticut and the towns and cities in the southeastern region of Connecticut subsequently donated land and provided funding to establish a military installation to fulfil the Nation's need for a naval facility on the Atlantic coast;

Whereas, on April 11, 1868, the Navy accepted the deed of gift of land from Connecticut to establish a naval yard and storage depot along the eastern shore of the Thames River in Groton, Connecticut;

Whereas, between 1868 and 1912, the New London Navy Yard supported a diverse range of missions, including berthing inactive Civil War era ironclad warships and serving as a coaling station for refueling naval ships traveling in New England waters;

Whereas Congress rejected the Navy's proposal to close New London Navy Yard in 1912, following an impassioned effort by Congressman Edwin W. Higgins, who stated that this "action proposed is not only unjust but unreasonable and unsound as a military proposition";

Whereas the outbreak of World War I and the enemy use of submarines to sink allied military and civilian ships in the Atlantic sparked a new focus on developing submarine capabilities in the United States;

Whereas October 18, 1915, marked the arrival at the New London Navy Yard of the

submarines G-1, G-2, and G-4 under the care of the tender USS OZARK, soon followed by the arrival of submarines E-1, D-1, and D-3 under the care of the tender USS TONOPAH, and on November 1, 1915, the arrival of the first ship built as a submarine tender, the USS FULTON (AS-1);

Whereas, on June 21, 1916, Commander Yeates Stirling assumed the command of the newly designated Naval Submarine Base New London, the New London Submarine Flotilla, and the Submarine School;

Whereas, in the 100 years since the arrival of the first submarines to the base, Naval Submarine Base New London has grown to occupy more than 680 acres along the east side of the Thames River, with more than 160 major facilities, 15 nuclear submarines, and more than 70 tenant commands and activities, including the Submarine Learning Center, Naval Submarine School, the Naval Submarine Medical Research Laboratory, the Naval Undersea Medical Institute, and the newly established Undersea Warfare Development Center;

Whereas, in addition to being the site of the first submarine base in the United States, Connecticut was home to the foremost submarine manufactures of the time, the Lake Torpedo Boat Company in Bridgeport and the Electric Boat Company in Groton, which later became General Dynamics Electric Boat;

Whereas General Dynamics Electric Boat, its talented workforce, and its Connecticut-based and nationwide network of suppliers have delivered more than 200 submarines from its current location in Groton, Connecticut, including the first nuclear-powered submarine, the USS NAUTILUS (SSN 571), and nearly half of the nuclear submarines ever built by the United States;

Whereas the Submarine Force Library and Museum, located adjacent to Naval Submarine Base New London in Groton, Connecticut, is the only submarine museum operated by the United States Navy and today serves as the primary repository for artifacts, documents, and photographs relating to the bold and courageous history of the Submarine Force and highlights as its core exhibit the historic ship Nautilus following her retirement from service;

Whereas, reflecting the close ties between Connecticut and the Navy that began with the gift of land that established the base, the State of Connecticut has set aside \$40,000,000 in funding for critical infrastructure investments to support the mission of the base, including construction of a new dive locker building, expansion of the Submarine Learning Center, and modernization of energy infrastructure;

Whereas, on September 29, 2015, Connecticut Governor Dannel Malloy designated October 2015 through October 2016 as Connecticut's Submarine Century, a year-long observance that celebrates 100 years of submarine activity in Connecticut, including the Town of Groton's distinction as the Submarine Capital of the World, to coincide with the centennial anniversary of the establishment of Naval Submarine Base New London and the Naval Submarine School;

Whereas Naval Submarine Base New London still proudly proclaims its motto of "The First and Finest"; and

Whereas Congressman Higgins' statement before Congress in 1912 that "Connecticut stands ready, as she always has, to bear her part of the burdens of the national defense" remains true today: Now, therefore, be it

*Resolved*, That the Senate—

(1) commends the long standing dedication and contribution to the Navy and submarine force by the people of Connecticut, both through the initial deed of gift that established what would become Naval Submarine

Base New London and through their ongoing commitment to support the mission of the base and the Navy personnel assigned to it;

(2) honors the submariners who have trained and served at Naval Submarine Base New London throughout its history in support of the Nation's security and undersea superiority;

(3) recognizes the contribution of the industry and workforce of Connecticut in designing, building, and sustaining the Navy's submarine fleet; and

(4) encourages the recognition of Connecticut's Submarine Century by Congress, the Navy, and the American people by honoring the contribution of the people of Connecticut to the defense of the United States and the important role of the submarine force in safeguarding the security of the United States for more than a century.

#### AMENDMENTS SUBMITTED AND PROPOSED

SA 2748. Mr. PORTMAN (for Mr. ALEXANDER) proposed an amendment to the bill H.R. 639, to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

#### TEXT OF AMENDMENTS

**SA 2748.** Mr. PORTMAN (for Mr. ALEXANDER) proposed an amendment to the bill H.R. 639, to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing; as follows:

Strike all after the enacting clause and insert the following:

##### SECTION 1. SHORT TITLE.

This Act may be cited as the "Improving Regulatory Transparency for New Medical Therapies Act".

##### SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW FDA-APPROVED DRUGS.

###### (a) EFFECTIVE DATE OF APPROVAL.—

(1) EFFECTIVE DATE OF DRUG APPROVAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

“(X) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

“(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

“(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term ‘date of approval’ shall mean the later of—

“(A) the date an application under subsection (b) is approved under subsection (c); or

“(B) the date of issuance of the interim final rule controlling the drug.”

(2) EFFECTIVE DATE OF APPROVAL OF BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

“(n) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

“(1) IN GENERAL.—In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act.

“(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), references to the date of approval of such application, or licensure of the product subject to such application, shall mean the later of—

“(A) the date an application is approved under subsection (a); or

“(B) the date of issuance of the interim final rule controlling the biological product.”

(3) EFFECTIVE DATE OF APPROVAL OF ANIMAL DRUGS.—

(A) IN GENERAL.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

“(q) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

“(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

“(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term ‘date of approval’ shall mean the later of—

“(A) the date an application under subsection (b) is approved under subsection (c); or

“(B) the date of issuance of the interim final rule controlling the drug.”

(B) CONDITIONAL APPROVAL.—Section 571(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc(d)) is amended by adding at the end the following:

“(4)(A) In the case of an application under subsection (a) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, conditional approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

“(B) For purposes of this section, with respect to an application described in subparagraph (A), the term ‘date of approval’ shall mean the later of—

“(i) the date an application under subsection (a) is conditionally approved under subsection (b); or

“(ii) the date of issuance of the interim final rule controlling the drug.”

(C) INDEXING OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS.—Section 572 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc-1) is amended by adding at the end the following:

“(k) In the case of a request under subsection (d) to add a drug to the index under subsection (a) with respect to a drug for which the Secretary provides notice to the person filing the request that the Secretary intends to issue a scientific and medical

evaluation and recommend controls under the Controlled Substances Act, a determination to grant the request to add such drug to the index shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.”

(4) DATE OF APPROVAL FOR DESIGNATED NEW ANIMAL DRUGS.—Section 573(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc-2(c)) is amended by adding at the end the following:

“(3) For purposes of determining the 7-year period of exclusivity under paragraph (1) for a drug for which the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, the drug shall not be considered approved or conditionally approved until the date that the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.”

(b) SCHEDULING OF NEWLY APPROVED DRUGS.—Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by inserting after subsection (i) the following:

“(j)(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 202(b) using the procedures described in paragraph (3).

“(2) The date described in this paragraph shall be the later of—

“(A) the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary of Health and Human Services in accordance with subsection (b); or

“(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an application under section 505(c), 512, or 571 of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act, or indexed a drug under section 572 of the Federal Food, Drug, and Cosmetic Act, with respect to the drug described in paragraph (1).

“(3) A rule issued by the Attorney General under paragraph (1) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 202(b).”

(c) EXTENSION OF PATENT TERM.—Section 156 of title 35, United States Code, is amended—

(1) in subsection (d)(1), in the matter preceding subparagraph (A), by inserting “, or in the case of a drug product described in subsection (i), within the sixty-day period beginning on the covered date (as defined in subsection (i))” after “marketing or use”; and

(2) by adding at the end the following:

“(i)(1) For purposes of this section, if the Secretary of Health and Human Services provides notice to the sponsor of an application or request for approval, conditional approval, or indexing of a drug product for which the Secretary intends to recommend controls under the Controlled Substances Act, beginning on the covered date, the drug product shall be considered to—