

“(A) have been approved or indexed under the relevant provision of the Public Health Service Act or Federal Food, Drug, and Cosmetic Act; and

“(B) have permission for commercial marketing or use.

“(2) In this subsection, the term ‘covered date’ means the later of—

“(A) the date an application is approved—

“(i) under section 351(a)(2)(C) of the Public Health Service Act; or

“(ii) under section 505(b) or 512(c) of the Federal Food, Drug, and Cosmetic Act;

“(B) the date an application is conditionally approved under section 571(b) of the Federal Food, Drug, and Cosmetic Act;

“(C) the date a request for indexing is granted under section 572(d) of the Federal Food, Drug, and Cosmetic Act; or

“(D) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act.”

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

“(i)(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

“(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.”

SEC. 4. RE-EXPORTATION AMONG MEMBERS OF THE EUROPEAN ECONOMIC AREA.

Section 1003 of the Controlled Substances Import and Export Act (21 U.S.C. 953) is amended—

(1) in subsection(f)—

(A) in paragraph (5)—

(i) by striking “(5)” and inserting “(5)(A)”;

(ii) by inserting “, except that the controlled substance may be exported from a second country that is a member of the European Economic Area to another country that is a member of the European Economic Area, provided that the first country is also a member of the European Economic Area” before the period at the end; and

(iii) by adding at the end the following:

“(B) Subsequent to any re-exportation described in subparagraph (A), a controlled substance may continue to be exported from any country that is a member of the European Economic Area to any other such country, if—

“(i) the conditions applicable with respect to the first country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country from which the controlled substance is exported pursuant to this paragraph; and

“(ii) the conditions applicable with respect to the second country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country to which the controlled substance is exported pursuant to this paragraph.”; and

(B) in paragraph (6)—

(i) by striking “(6)” and inserting “(6)(A)”;

and

(ii) by adding at the end the following:

“(B) In the case of re-exportation among members of the European Economic Area, within 30 days after each re-exportation, the person who exported the controlled substance from the United States delivers to the Attorney General—

“(i) documentation certifying that such re-exportation has occurred; and

“(ii) information concerning the consignee, country, and product.”; and

(2) by adding at the end the following:

“(g) LIMITATION.—Subject to paragraphs (5) and (6) of subsection (f) in the case of any controlled substance in schedule I or II or any narcotic drug in schedule III or IV, the Attorney General shall not promulgate nor enforce any regulation, subregulatory guidance, or enforcement policy which impedes re-exportation of any controlled substance among European Economic Area countries, including by promulgating or enforcing any requirement that—

“(1) re-exportation from the first country to the second country or re-exportation from the second country to another country occur within a specified period of time; or

“(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States or prior to each re-exportation among members of the European Economic Area.”.

The PRESIDING OFFICER. The Senator from Ohio.

WOUNDED WARRIOR FEDERAL LEAVE ACT OF 2015

Mr. PORTMAN. Madam President, I ask unanimous consent that the Committee on Homeland Security and Governmental Affairs be discharged from further consideration of H.R. 313 and the Senate proceed to its immediate consideration.

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

The clerk will report the bill by title.

The senior assistant legislative clerk read as follows:

A bill (H.R. 313) to amend title 5, United States Code, to provide leave to any new Federal employee who is a veteran with a service-connected disability rated at 30 percent or more for purposes of undergoing medical treatment for such disability, and for other purposes.

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

Mr. PORTMAN. I ask unanimous consent that the bill be 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. 313) was ordered to a third reading, was read the third time, and passed.

IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT

Mr. PORTMAN. Madam President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be discharged from further consideration of H.R. 639 and the

Senate proceed to its immediate consideration.

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

The clerk will report the bill by title.

The senior assistant legislative clerk read as follows:

A 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.

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

Mr. PORTMAN. I ask unanimous consent that the substitute amendment, which is at the desk, be considered and agreed to, the bill, as amended, be 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. 2748) 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. 639), as amended, was passed.

CONGRATULATING THE MINNESOTA LYNX ON THEIR VICTORY IN THE 2015 WOMEN’S NATIONAL BASKETBALL ASSOCIATION FINALS

Mr. PORTMAN. Madam President, I ask unanimous consent that the Senate proceed to the immediate consideration of S. Res. 297, 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. 297) congratulating the Minnesota Lynx on their victory in the 2015 Women’s National Basketball Association Finals.

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

Mr. PORTMAN. Madam 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. 297) was agreed to.

The preamble was agreed to.

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

ORDERS FOR TUESDAY,

OCTOBER 27, 2015

Mr. PORTMAN. Madam President, I ask unanimous consent that when the

Senate completes its business today, it adjourn until 10 a.m., Tuesday, October 27; that following the prayer and pledge, the morning hour be deemed expired, the Journal of proceedings be approved to date, and the time for the two leaders be reserved for their use later in the day; that following leader remarks, the Senate resume consideration of S. 754, with the time until 11 a.m. equally divided between the two leaders or their designees; finally, that notwithstanding the provisions of rule XXII, there be 2 minutes of debate equally divided prior to each vote, and that all votes after the first vote in each series be 10 minutes each.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

ORDER FOR ADJOURNMENT

Mr. PORTMAN. Madam President, if there is no further business to come before the Senate, I ask unanimous consent that it stand adjourned under the previous order, following the remarks of Senator FRANKEN.

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

The Senator from Minnesota.

Mr. FRANKEN. Madam President, I ask unanimous consent to speak for 6 minutes.

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

CYBERSECURITY INFORMATION SHARING BILL

Mr. FRANKEN. Madam President, tomorrow we will vote on my amendment to the Cybersecurity Information Sharing Act, or CISA. I am proud to be joined on this amendment by Senators LEAHY, DURBIN, and WYDEN, each of whom has worked to try to ensure that any cyber legislation passed by this body is effective and adequately safeguards the privacy and civil liberties of the American people.

My amendment tightens the definitions of the terms “cyber security threat” and “cyber threat indicator” in the bill. These changes will help ensure that CISA’s broad authorities are not triggered in circumstances where no real cyber threats are present. This makes the bill more privacy protected and more likely to work effectively.

The amendment is supported by more than 30 civil society organizations, from the American Civil Liberties Union to prominent Libertarian groups like R Street. As I will describe, it addresses specific concerns that have been raised by security experts, major tech companies, and even the Department of Homeland Security.

Under CISA, companies are authorized to monitor users online, share information with one another and with the Federal Government, and deploy defensive measures—all to protect against “cyber security threats.” Any action that may result in any unauthorized effort to adversely impact cyber security can be deemed a cyber security threat; that is, may result. That sets the lowest possible standard for determining when actions under CISA are justified, and that is a problem. It sets us up for the oversharing of information, or worse it jeopardizes privacy and threatens to hinder our cyber defense efforts by increasing the noise-to-signal ratio.

My amendment would clarify that a threat is any action at least reasonably likely—reasonably likely—to result in an unauthorized effort to adversely impact cyber security. That definition gives companies ample flexibility to act on threats and ensures Americans that CISA isn’t a free pass to share people’s personal information when there is no threat.

CISA’s definition of cyber threat indicator has also been criticized by security experts, by companies such as Mozilla and, again, even by DHS, which has called the definition “expansive” and said that expansive definition heightens concerns raised by the bill.

My amendment addresses the two parts of the definition that experts have suggested are the most likely to open the door to the sharing of extraneous information. First, as drafted, CISA would let companies share people’s communications if they believe that the files have been harmed in a cyber attack or could potentially—potentially—be harmed by a perceived threat. The latter is especially problematic. The range of information that could be shared as evidence of potential harm is vast, and, as experts have explained, unnecessary to the technical work of identifying cyber threats. My amendment continues to allow compa-

nies to share information that reveals harms caused by a cyber incident but doesn’t extend this to conjecture about hypothetical potential harms, which is unnecessarily broad.

Finally, my amendment eliminates a troubling loophole in the cyber threat indicator definition. In addition to letting companies share information that reveals certain specified attributes or features of cyber threats, CISA also lets them share information that reveals “any other attribute of a cybersecurity threat” if the disclosure of that attribute is legal. Bill supporters claim that this final clause adequately limits the scope of this provision, but looking at whether disclosure of a threat attribute is lawful is an unclear and unhelpful standard. Privacy law is about protecting information, not threat attributes. So my amendment clarifies that companies can share information in this catchall category only if it is legal to share the information being provided. It is a technical change, but it matters.

This amendment represents a real effort to find common ground for moving forward. Quite frankly, it doesn’t do all the work that needs to be done to limit the definitions in this act, but it makes necessary changes—necessary changes—to improve the legislation, both for the sake of privacy and ultimately security.

I urge my colleagues to support amendment No. 2612.

I yield the floor.

ADJOURNMENT UNTIL 10 A.M. TOMORROW

The PRESIDING OFFICER. Under the previous order, the Senate stands adjourned until 10 a.m. tomorrow.

Thereupon, the Senate, at 6:13 p.m., adjourned until Tuesday, October 27, 2015, at 10 a.m.

CONFIRMATION

Executive nomination confirmed by the Senate October 26, 2015:

THE JUDICIARY

LAWRENCE JOSEPH VILARDO, OF NEW YORK, TO BE UNITED STATES DISTRICT JUDGE FOR THE WESTERN DISTRICT OF NEW YORK.