

(3) in subsection (g), by inserting before the period “, except that no sponsor of a rare pediatric disease product application may receive more than one priority review voucher issued under any section of this Act with respect to the drug for which the application is made.”

(b) RULE OF CONSTRUCTION.—Nothing in this Act, or the amendments made by this Act, shall be construed to affect the validity of a priority review voucher that was issued under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) before the date of enactment of this Act.

SEC. 3. GAO REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the effectiveness of awarding priority review vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) in providing incentives for the development of drugs that treat or prevent rare pediatric diseases (as defined in subsection (a)(3) of such section) that would not otherwise have been developed. In conducting such study, the Comptroller General shall examine the following:

(1) The indications for which each drug for which a priority review voucher was awarded under such section 529 was approved under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(2) Whether the priority review voucher impacted sponsors’ decisions to invest in developing a drug to treat or prevent a rare pediatric disease.

(3) An analysis of the drugs for which such priority review vouchers were used, which shall include—

(A) the indications for which such drugs were approved under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a));

(B) whether unmet medical needs were addressed through the approval of such drugs, including, for each such drug—

(i) if an alternative therapy was previously available to treat the indication; and

(ii) if the drug provided a benefit or advantage over another available therapy;

(C) the number of patients potentially treated by such drugs;

(D) the value of the priority review voucher if transferred; and

(E) the length of time between the date on which a priority review voucher was awarded and the date on which it was used.

(4) With respect to the priority review voucher program under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff)—

(A) the resources used by the Food and Drug Administration in implementing such program, including the effect of such program on the Food and Drug Administration’s review of drugs for which a priority review voucher was not awarded or used;

(B) the impact of the program on the public health as a result of the review and approval of drugs that received a priority review voucher and products that were the subject of a redeemed priority review voucher; and

(C) alternative approaches to improving such program so that the program is appropriately targeted toward providing incentives for the development of clinically important drugs that—

(i) prevent or treat rare pediatric diseases; and

(ii) would likely not otherwise have been developed to prevent or treat such diseases.

(b) REPORT.—Not later than January 31, 2022, the Comptroller General of the United

States 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 containing the results of the study of conducted under subsection (a).

The bill was ordered to be read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

FEDERAL AVIATION ADMINISTRATION VETERAN TRANSITION IMPROVEMENT ACT OF 2016

Mr. LOBIONDO. Mr. Speaker, I ask unanimous consent to take from the Speaker’s table the bill (S. 2683) to include disabled veteran leave in the personnel management system of the Federal Aviation Administration, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

The text of the bill is as follows:

S. 2683

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

SECTION 1. SHORT TITLE.

This Act may be cited as the “Federal Aviation Administration Veteran Transition Improvement Act of 2016”.

SEC. 2. INCLUSION OF DISABLED VETERAN LEAVE IN FEDERAL AVIATION ADMINISTRATION PERSONNEL MANAGEMENT SYSTEM.

(a) IN GENERAL.—Section 40122(g)(2) of title 49, United States Code, is amended—

(1) in subparagraph (H), by striking “; and” and inserting a semicolon;

(2) in subparagraph (I)(iii), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following:

“(J) subject to paragraph (4) of this subsection, section 6329, relating to disabled veteran leave.”.

(b) CERTIFICATION OF LEAVE.—Section 40122(g) of such title is amended—

(1) by redesignating paragraph (4) as paragraph (5); and

(2) by inserting after paragraph (3) the following:

“(4) CERTIFICATION OF DISABLED VETERAN LEAVE.—In order to verify that leave credited to an employee pursuant to paragraph (2)(J) is used for treating a service-connected disability, that employee shall, notwithstanding section 6329(c) of title 5, submit to the Assistant Administrator for Human Resource Management of the Federal Aviation Administration certification, in such form and manner as the Administrator of the Federal Aviation Administration may prescribe, that the employee used that leave for purposes of being furnished treatment for that disability by a health care provider.”.

(c) APPLICATION.—The amendments made by this section shall apply with respect to any employee of the Federal Aviation Administration hired on or after the date that is one year after the date of the enactment of this Act.

(d) POLICIES AND PROCEDURES.—Not later than 270 days after the date of the enactment of this Act, the Administrator of the Federal Aviation Administration shall prescribe policies and procedures to carry out the amendments made by this section that are com-

parable, to the maximum extent practicable, to the regulations prescribed by the Office of Personnel Management under section 6329 of title 5, United States Code.

The bill was ordered to be read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

VETERANS DAY MOMENT OF SILENCE ACT

Mr. MILLER of Florida. Mr. Speaker, I ask unanimous consent that the Committee on Veterans’ Affairs be discharged from further consideration of the bill (S. 1004) to amend title 36, United States Code, to encourage the nationwide observance of two minutes of silence each Veterans Day, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Florida?

There was no objection.

The text of the bill is as follows:

S. 1004

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

SECTION 1. SHORT TITLE.

This Act may be cited as the “Veterans Day Moment of Silence Act”.

SEC. 2. OBSERVANCE OF VETERANS DAY.

(a) TWO MINUTES OF SILENCE.—Chapter 1 of title 36, United States Code, is amended by adding at the end the following new section: “§ 145. Veterans Day

“The President shall issue each year a proclamation calling on the people of the United States to observe two minutes of silence on Veterans Day in honor of the service and sacrifice of veterans throughout the history of the Nation, beginning at—

“(1) 3:11 p.m. Atlantic standard time;

“(2) 2:11 p.m. eastern standard time;

“(3) 1:11 p.m. central standard time;

“(4) 12:11 p.m. mountain standard time;

“(5) 11:11 a.m. Pacific standard time;

“(6) 10:11 a.m. Alaska standard time; and

“(7) 9:11 a.m. Hawaii-Aleutian standard time.”.

(b) CLERICAL AMENDMENT.—The table of sections for chapter 1 of title 36, United States Code, is amended by adding at the end the following new item:

“145. Veterans Day.”.

Mr. LYNCH. Mr. Speaker, I rise today in support of S. 1004, the Veterans Day Moment of Silence Act. I am proud to have introduced the House version of this bill, H.R. 995.

This bipartisan legislation calls for two minutes of silence every Veterans Day. The set time of 2:11 P.M., Eastern Standard Time, will allow all Americans from coast to coast and Puerto Rico to come together as one nation to reflect on the service of our veterans, past and present. Generations of brave men and women have served the United States of America with honor, risking their lives to keep us safe and free. They deserve our support and, especially, our gratitude.

Mr. Speaker, our servicemembers have made, and continue to make, immense sacrifices. They leave their loved ones behind, operate in some of the most dangerous places in the world, and put themselves in harm’s way to defend our nation. I have had the

honor and pleasure of meeting with servicemembers during my Congressional Delegations abroad. I am always moved by their professionalism, courage, and most especially, their dedication to their families, fellow service members, and country. This Moment of Silence legislation will send a powerful message of appreciation to our veterans for all that they do on behalf of our nation.

I would like to express my thanks to the leadership of the Veterans Affairs Committee, as well as to the bipartisan group of cosponsors who were steadfast in their support of H.R. 995. I am grateful to Senators KIRK and DURBIN for their leadership and stewardship of this initiative on the Senate side. I also wish to thank Daniel and Michael Bendetson, along with their father, Dr. Peter Bendetson, who first approached me with the concept of this tribute and have worked tirelessly for years to bring this proposal to fruition. Finally, I would like to thank all the veterans in the Eighth District of Massachusetts and across America, in whose honor I am proud to have introduced and supported the Veterans Day Moment of Silence Act.

The bill was ordered to be read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. MILLER of Florida. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days to revise and extend their remarks and include extraneous materials on S. 1004.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Florida?

There was no objection.

EXPRESSING PROFOUND CONCERN ABOUT THE ONGOING POLITICAL, ECONOMIC, SOCIAL AND HUMANITARIAN CRISIS IN VENEZUELA

Ms. ROS-LEHTINEN. Mr. Speaker, I ask unanimous consent that the Committee on Foreign Affairs be discharged from further consideration of the resolution (H. Res. 851) expressing profound concern about the ongoing political, economic, social and humanitarian crisis in Venezuela, urging the release of political prisoners, and calling for respect of constitutional and democratic processes, and ask for its immediate consideration in the House.

The Clerk read the title of the resolution.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Florida?

Ms. WASSERMAN SCHULTZ. Mr. Speaker, reserving the right to object, although I do not intend to object, I am proud to be the sponsor of H. Res. 851, which expresses profound concern about the shameful and rampant corruption of President Maduro's government and the plight of the Venezuelan people.

The Maduro regime's efforts to silence political opposition leaders, including by jailing Leopoldo Lopez and Daniel de Ceballos, are unconscionable.

And just last week, the National Electoral Council announced an outrageously high barrier to the referendum on his government that millions of Venezuelans are demanding.

His flagrant misconduct has brought a series of devastating crises to Venezuela. Families all across the country are starving. Their local store shelves are barren, many of them empty of both food and lifesaving medicine.

And Maduro still refuses to listen to the will of his people. They are crying out for their voices to be heard and their rights respected, and we must ensure they are not crying out in vain.

I am proud to cosponsor this legislation with my colleague, the gentlewoman from Florida (Ms. ROS-LEHTINEN).

I withdraw my reservation of objection.

The SPEAKER pro tempore. The reservation is withdrawn.

Is there further objection to the request of the gentlewoman from Florida (Ms. ROS-LEHTINEN)?

There was no objection.

The text of the resolution is as follows:

H. RES. 851

Whereas the deterioration of basic governance and the economic crisis in Venezuela have reached deeply troubling levels, which in turn have led to an unprecedented humanitarian situation in Venezuela where millions of people are suffering from severe shortages of essential medicines and basic food products;

Whereas Venezuela lacks more than 80 percent of the basic medical supplies and equipment needed to treat its population, including medicine to treat chronic illnesses and cancer as well as basic antibiotics, and 85 percent of pharmacies are at risk of bankruptcy, according to the Venezuelan Pharmaceutical Federation;

Whereas, despite the massive shortages of basic foodstuffs and essential medicines, President of Venezuela Nicolas Maduro has rejected repeated requests from the majority of members of the National Assembly and civil society organizations to bring humanitarian aid into the country;

Whereas the International Monetary Fund assesses that, in Venezuela, inflation reached 275 percent and the gross domestic product contracted 5.7 percent in 2015, and further projects that inflation will reach 720 percent and the gross domestic product will contract an additional 8 percent in 2016;

Whereas Venezuela's political, economic, and humanitarian crisis is fueling social tensions that are resulting in growing incidents of public unrest, looting, and violence among citizens;

Whereas these social distortions are taking place amidst an alarming climate of violence as Caracas continues to have the highest per capita homicide rate in the world at 120 per 100,000 citizens, according to the United Nations Office on Drug and Crime;

Whereas the deterioration of governance in Venezuela has been exacerbated by widespread public corruption and the involvement of public officials in illicit narcotics trafficking and related money laundering, which has led to indictments by the United States Department of Justice and ongoing investigations by the United States Department of the Treasury and the United States Drug Enforcement Administration;

Whereas domestic and international human rights groups recognize more than 85

political prisoners in Venezuela, including opposition leader and former Chacao mayor Leopoldo Lopez, Judge Maria Lourdes Afiuni, Caracas Mayor Antonio Ledezma, former Zulia governor Manuel Rosales, and former San Cristobal mayor Daniel Ceballos;

Whereas, in December 2015, the people of Venezuela elected the opposition coalition (Mesa de Unidad Democrática) to a two-thirds majority in the unicameral National Assembly, with 112 out of the 167 seats compared with 55 seats for the government's Partido Socialista Unido de Venezuela party;

Whereas, in late December 2015, the outgoing National Assembly increased the number of seats in the Supreme Court of Venezuela and confirmed magistrates politically aligned with the Maduro Administration and, thereafter, the expanded Supreme Court has blocked four legislators, including 3 opposition legislators, from taking office;

Whereas, during the first 6 months of the new legislature, the Supreme Court has repeatedly issued politically motivated judgments to overturn legislation passed by the democratically elected National Assembly and block internal legislative procedures;

Whereas, in 2016, President Maduro has utilized emergency and legislative decree powers to bypass the National Assembly, which, alongside the actions of the Supreme Court, have severely undermined the principles of separation of powers in Venezuela;

Whereas, in May 2016, Organization of American States Secretary General Luis Almagro presented a 132-page report outlining grave alterations of the democratic order in Venezuela and invoked Article 20 of the Inter-American Democratic Charter, which calls on the OAS Permanent Council "to undertake a collective assessment of the situation";

Whereas, in June 2016, at a joint press conference with Prime Minister Justin Trudeau of Canada and President Enrique Peña Nieto of Mexico, President Barack Obama stated, "Given the very serious situation in Venezuelan people, together we're calling on the government and opposition to engage in meaningful dialogue and urge the Venezuelan government to respect the rule of law and the authority of the National Assembly"; and

Whereas, at the joint press conference with Prime Minister Justin Trudeau and President Peña Nieto, President Barack Obama continued, "Political prisoners should be released. The democratic process should be respected and that includes legitimate efforts to pursue a recall referendum consistent with Venezuelan law.": Now, therefore, be it

Resolved, That the House of Representatives—

(1) expresses its profound concern about widespread shortages of essential medicines and basic food products faced by the people of Venezuela, and urges President Maduro to permit the delivery of humanitarian assistance;

(2) calls on the Government of Venezuela to immediately release all political prisoners, to provide protections for freedom of expression and assembly, and to respect internationally recognized human rights;

(3) supports meaningful efforts towards a dialogue that leads to respect for Venezuela's constitutional mechanisms and resolves the country's political, economic, social, and humanitarian crisis;

(4) affirms its support for OAS Secretary General Almagro's invocation of Article 20 of the Inter-American Democratic Charter and urges the OAS Permanent Council, which represents all of the organization's member states, to undertake a collective assessment of the constitutional and democratic order in Venezuela;