□ 1909

So (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

HONOR AMERICA'S GUARD-RESERVE RETIREES ACT

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 1384) to amend title 38, United States Code, to recognize the service in the reserve components of certain persons by honoring them with status as veterans under law, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Pennsylvania (Mr. COSTELLO) that the House suspend the rules and pass the bill.

This is a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 407, nays 0, not voting 26, as follows:

[Roll No. 628]

YEAS—407

Abraham
Adams
Aderholt
Aguilar
Allen
Amash
Ashford
Babin
Barletta
Barr
Barton
Bass
Beatty
Becerra
Benishek
Bera
Beyer
Bilirakis
Bishop (GA)
Bishop (MI)
Bishop (UT)
Black
Blackburn
Blum
Blumenauer
Bonamici
Bost
Boustany
Boyle, Brendan F.
Brady (PA)
Brady (TX)
Brat
Bridenstine
Brooks (AL)
Brooks (IN)
Brown (FL)
Brownley (CA)
Buchanan
Buck
Bucshon
Burgess
Bustos
Butterfield
Byrne
Calvert
Capps
Capuano
Cárdenas
Carney
Carson (IN)
Carter (GA)
Carter (TX)
Cartwright
Castor (FL)
Castro (TX)
Chabot
Chaffetz
Chu, Judy
Cicilline
Clark (MA)
Clarke (NY)
Clawson (FL)
Clay
Clyburn
Coffman
Cohen
Cole
Collins (GA)
Collins (NY)
Comstock
Conaway
Connolly
Conyers
Cook
Cooper
Costa
Costello (PA)
Courtney
Cramer
Crawford
Crenshaw
Crowley
Cuellar
Culberson
Cummings
Curbelo (FL)
Davis (CA)
Davis, Danny
Davis, Rodney
DeGette
Delaney
DeLauro
DelBene
Denham
Dent
DeSantis
DeSaulnier
DesJarlais
Deutch
Diaz-Balart
Dingell
Doggett
Dold
Donovan
Doyle, Michael F.
Duckworth
Duffy
Duncan (SC)
Duncan (TN)
Edwards
Ellison
Ellmers (NC)
Emmer (MN)
Engel
Esty
Farenthold
Farr
Fincher
Fitzpatrick
Fleischmann
Fleming
Flores
Forbes
Fortenberry
Foster
Foxx
Frankel (FL)
Franks (AZ)
Frelinghuysen
Fudge
Gabbard
Gallego
Garamendi
Garrett
Gibbs
Gibson
Gohmert
Goodlatte
Gosar
Gowdy
Graham
Granger
Graves (GA)
Graves (LA)
Graves (MO)
Grayson
Green, Al
Green, Gene
Griffith
Grijalva
Grothman
Guinta
Guthrie
Hahn
Hanna
Hardy
Harper
Harris
Hartzler
Hastings
Heck (NV)
Heck (WA)
Hensarling
Herrera Beutler
Hice, Jody B.
Higgins
Hill
Himes
Holding
Honda
Hoyer
Huelskamp
Huffman
Huizenga (MI)
Hunter
Hurd (TX)
Hurt (VA)
Israel
Issa
Jackson Lee
Jeffries
Jenkins (KS)
Jenkins (WV)
Johnson (GA)
Johnson (OH)
Johnson, E. B.
Johnson, Sam
Jolly
Jones
Jordan
Joyce
Kaptur
Katko
Keating
Kelly (IL)
Kelly (MS)
Kelly (PA)
Kennedy
Kildee
Kilmer
Kind
King (NY)
Kinzinger (IL)
Kirkpatrick
Kline
Knight
Kuster
Labrador
LaHood
LaMalfa
Lamborn
Lance
Langevin
Larsen (WA)
Larson (CT)
Latta
Lee
Levin
Lewis
Lipinski
LoBiondo
Loebsack
Lofgren
Long
Loudermilk
Love
Lowenthal
Lucas
Luetkemeyer
Lujan Grisham (NM)
Luján, Ben Ray (NM)
Lummis
Lynch
MacArthur
Maloney, Carolyn
Maloney, Sean
Marino
Massie
Matsui
McCarthy
McCaul
McClintock
McCollum
McDermott
McHenry
McKinley
McMorris Rodgers
McNerney
McSally
Meadows
Meehan
Meeks
Meng
Messer
Mica
Miller (FL)
Miller (MI)
Moolenaar
Mooney (WV)
Moore
Moulton
Mullin
Mulvaney
Murphy (FL)
Murphy (PA)
Nadler
Napolitano
Neal
Neugebauer
Newhouse
Noem
Nolan
Norcross
Nugent
Nunes
O'Rourke
Olson
Palazzo
Pallone
Palmer
Pascrell
Paulsen
Payne
Pearce
Pelosi
Perlmutter
Perry
Peters
Peterson
Pingree
Pittenger
Pitts
Pocan
Poe (TX)
Poliquin
Polis
Pompeo
Posey
Price (NC)
Price, Tom
Quigley
Rangel
Ratcliffe
Reed
Reichert
Renacci
Ribble
Rice (NY)
Rice (SC)
Rigell
Roby
Roe (TN)
Rogers (AL)
Rogers (KY)
Rokita
Rooney (FL)
Ros-Lehtinen
Roskam
Ross
Rothfus
Rouzer
Roybal-Allard
Royce
Ruiz
Russell
Ryan (OH)
Salmon
Sánchez, Linda T.
Sanford
Sarbanes
Scalise
Schiff
Schrader
Schweikert
Scott (VA)
Scott, Austin
Sensenbrenner
Serrano
Sessions
Sewell (AL)
Sherman
Shimkus
Shuster
Simpson
Sinema
Sires
Slaughter
Smith (MO)
Smith (NE)
Smith (NJ)
Smith (TX)
Smith (WA)
Speier
Stefanik
Stewart
Stivers
Stutzman
Swalwell (CA)
Takano
Thompson (CA)
Thompson (MS)
Thompson (PA)
Thornberry
Tiberi
Tipton
Tonko
Torres
Trott
Tsongas
Turner
Upton
Valadao
Van Hollen
Vargas
Veasey
Vela
Velázquez
Visclosky
Walberg
Walden
Walker
Walorski
Walters, Mimi
Walz
Wasserman Schultz
Waters, Maxine
Watson Coleman
Weber (TX)
Webster (FL)
Welch
Wenstrup
Westerman
Westmoreland
Williams
Wilson (FL)
Wilson (SC)
Wittman
Womack
Woodall
Yarmuth
Yoder
Yoho
Young (AK)
Young (IA)
Young (IN)
Zeldin
Zinke

NOT VOTING—26

Amodei
Cleaver
DeFazio
Eshoo
Fattah
Gutiérrez
Hinojosa
Hudson
Hultgren
King (IA)
Lawrence
Lieu, Ted
Lowey
Marchant
McGovern
Richmond
Rohrabacher
Ruppersberger
Rush
Sanchez, Loretta
Schakowsky
Scott, David
Takai
Titus
Wagner
Whitfield

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining.

□ 1917

So (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

PERSONAL EXPLANATION

Mrs. LAWRENCE. Mr. Speaker, I was unable to vote due to the necessity of my attending to representational duties and participation in Michigan. Had I been in attendance, I would have voted: "yes"—H.R. 308—Keep the Promise Act, "yes"—H.R. 1338—Dignified Interment of Our Veterans' Act of 2015, "yes"—H.R. 1384—Honor America's Guard-Reserve Retirees Act.

PERSONAL EXPLANATION

Ms. SCHAKOWSKY. Mr. Speaker, this evening, I was unavoidably detained and unable to cast votes on the House floor. Had I been present, I would have voted "aye" on H.R. 1338 and H.R. 1384. I would have voted "nay" on H.R. 308.

PERSONAL EXPLANATION

Mr. FATTAH. Mr. Speaker, on the following rollcall Nos. I would have voted: "no" on rollcall 626, "yes" on rollcall 627, "yes" on rollcall 628.

PERSONAL EXPLANATION

Mr. DEFAZIO. Mr. Speaker, I was absent on November 16, 2015, due to recovery from eye surgery, and missed the following votes. Had I been present I would have voted:

On Motion to Suspend the Rules and Pass H.R. 308, I would have voted "present."

On Motion to Suspend the Rules and Pass H.R. 1338, I would have voted "aye."

On Motion to Suspend the Rules and Pass H.R. 1384, I would have voted "aye."

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 1737, REFORMING CFPB INDIRECT AUTO FINANCING GUIDANCE ACT; PROVIDING FOR CONSIDERATION OF H.R. 511, TRIBAL LABOR SOVEREIGNTY ACT OF 2015; AND FOR OTHER PURPOSES

Mr. COLE, from the Committee on Rules, submitted a privileged report (Rept. No. 114–340) on the resolution (H. Res. 526) providing for consideration of the bill (H.R. 1737) to nullify certain guidance of the Bureau of Consumer Financial Protection and to provide requirements for guidance issued by the Bureau with respect to indirect auto lending; providing for consideration of the bill (H.R. 511) to clarify the rights of Indians and Indian tribes on Indian lands under the National Labor Relations Act; and for other purposes, which was referred to the House Calendar and ordered to be printed.

REMOVAL OF NAME OF MEMBER AS COSPONSOR OF H.R. 1694

Mrs. BUSTOS. Mr. Speaker, I ask unanimous consent to remove my name as a cosponsor of H.R. 1694.

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

There was no objection.

IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT

Mr. GRIFFITH. Mr. Speaker, I ask unanimous consent to take from the Speaker's table 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, with the Senate amendment thereto, and concur in the Senate amendment.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will report the Senate amendment.

The Clerk read as follows:

Senate amendment:

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—

''(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: