

Watt	Welch	Woolsey
Waxman	Wilson (FL)	Yarmuth

NOT VOTING—9

Bachus	Lewis (CA)	Sánchez, Linda
Becerra	Miller (FL)	T.
Dreier	Miller, Gary	
Jackson (IL)	Reed	

## ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

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

□ 1415

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated for:

Mr. BECERRA. Mr. Speaker, on June 20, 2012, I was unavoidably detained and missed rollcall vote 390. If present, I would have voted “yea” on rollcall vote 390.

# MOTION TO INSTRUCT CONFEREES ON H.R. 4348, SURFACE TRANSPORTATION EXTENSION ACT OF 2012, PART II

The SPEAKER pro tempore. The unfinished business is the vote on the motion to instruct on H.R. 4348 offered by the gentleman from Minnesota (Mr. WALZ) on which the yeas and nays were ordered.

The Clerk will redesignate the motion.

The Clerk redesignated the motion.

The SPEAKER pro tempore. The question is on the motion to instruct.

This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 386, nays 34, answered “present” 1, not voting 11, as follows:

[Roll No. 391]

YEAS—386

Ackerman	Braley (IA)	Costello
Adams	Brooks	Courtney
Aderholt	Brown (FL)	Cravaack
Akin	Buchanan	Crawford
Alexander	Bucshon	Crenshaw
Altmire	Buerkle	Critz
Amodei	Burgess	Crowley
Andrews	Burton (IN)	Cuellar
Austria	Butterfield	Cummings
Baca	Calvert	Davis (CA)
Bachmann	Cantor	Davis (IL)
Baldwin	Capito	Davis (KY)
Barber	Capps	DeFazio
Barletta	Capuano	DeGette
Barrow	Cardoza	DeLauro
Bartlett	Carnahan	Denham
Barton (TX)	Carney	Dent
Bass (NH)	Carson (IN)	DesJarlais
Becerra	Cassidy	Deutch
Benishek	Castor (FL)	Diaz-Balart
Berg	Chabot	Dicks
Berkley	Chaffetz	Dingell
Berman	Chandler	Doggett
Biggert	Chu	Dold
Bilbray	Cicilline	Donnelly (IN)
Bilirakis	Clarke (MI)	Doyle
Bishop (GA)	Clarke (NY)	Duffy
Bishop (NY)	Clay	Duncan (SC)
Black	Cleaver	Duncan (TN)
Blackburn	Clyburn	Edwards
Blumenauer	Coble	Ellison
Bonamici	Coffman (CO)	Ellmers
Bonner	Cohen	Emerson
Bono Mack	Cole	Engel
Boren	Connolly (VA)	Eshoo
Boswell	Conyers	Farenthold
Boustany	Cooper	Farr
Brady (PA)	Costa	Fattah

Filner	Larson (CT)	Rivera
Fitzpatrick	Latham	Roby
Flake	LaTourette	Roe (TN)
Fleischmann	Latta	Rogers (AL)
Fleming	Lee (CA)	Rogers (KY)
Forbes	Levin	Rogers (MI)
Fortenberry	Lewis (GA)	Rohrabacher
Frank (MA)	Lipinski	Rokita
Franks (AZ)	LoBiondo	Ros-Lehtinen
Frelinghuysen	Loeb	Roskam
Fudge	Lofgren, Zoe	Ross (AR)
Gallegly	Lowey	Ross (FL)
Garamendi	Lucas	Rothman (NJ)
Gardner	Luetkemeyer	Roybal-Allard
Gerlach	Luján	Royce
Gibbs	Lummis	Runyan
Gibson	Lungren, Daniel E.	Ruppersberger
Gonzalez	Lynch	Rush
Goodlatte	Mack	Ryan (OH)
Gosar	Maloney	Ryan (WI)
Gowdy	Manzullo	Sanchez, Loretta
Graves (GA)	Marchant	Sarbanes
Graves (MO)	Marino	Scalise
Green, Al	Markey	Schakowsky
Green, Gene	Matheson	Schiff
Griffin (AR)	Matsui	Schilling
Griffith (VA)	McCarthy (CA)	Schmidt
Grijalva	McCarthy (NY)	Schrader
Grimm	McCaul	Schwartz
Guinta	McCollum	Schweikert
Guthrie	McCotter	Scott (SC)
Gutierrez	McDermott	Scott (VA)
Hahn	McGovern	Scott, Austin
Hall	McHenry	Scott, David
Hanabusa	McIntyre	Sensenbrenner
Hanna	McKeon	Serrano
Harper	McKinley	Sewell
Harris	McMorris	Sherman
Hartzler	Rodgers	Shimkus
Hastings (FL)	McNerney	Shuler
Hastings (WA)	Meehan	Shuster
Hayworth	Meeks	Simpson
Heck	Mica	Sires
Heinrich	Michaud	Slaughter
Hensarling	Miller (MI)	Smith (NE)
Herger	Miller (NC)	Smith (NJ)
Herrera Beutler	Miller, George	Smith (TX)
Higgins	Moore	Smith (WA)
Himes	Moran	Southerland
Hinche	Mulvaney	Speier
Hinojosa	Murphy (CT)	Stark
Hirono	Murphy (PA)	Stivers
Hochul	Myrick	Stutzman
Holden	Nadler	Sullivan
Holt	Napolitano	Sutton
Honda	Neal	Terry
Hoyer	Noem	Thompson (CA)
Huelskamp	Nugent	Thompson (MS)
Hultgren	Nunes	Tiberi
Hunter	Nunnelee	Tierney
Hurt	Olson	Tipton
Israel	Oliver	Tonko
Issa	Owens	Towns
Jackson Lee	Palazzo	Tsongas
(TX)	Pallone	Turner (NY)
Jenkins	Pascarell	Turner (OH)
Johnson (GA)	Pastor (AZ)	Upton
Johnson (IL)	Paul	Van Hollen
Johnson (OH)	Paulsen	Velázquez
Johnson, E. B.	Pelosi	Visclosky
Johnson, Sam	Pence	Walberg
Jones	Perlmutter	Walden
Jordan	Peters	Walz (MN)
Kaptur	Peterson	Wasserman
Keating	Petri	Schultz
Kelly	Pingree (ME)	Waters
Kildee	Pitts	Watt
Kind	Platts	Waxman
King (IA)	Polis	West
King (NY)	Price (GA)	Whitfield
Kingston	Price (NC)	Wilson (FL)
Kinzinger (IL)	Quigley	Wilson (SC)
Kissell	Rahall	Wittman
Kline	Rangel	Wolf
Kucinich	Rehberg	Womack
Labrador	Reichert	Woodall
Lamborn	Renacci	Woolsey
Lance	Reyes	Yarmuth
Landry	Richardson	Yoder
Langevin	Richmond	Young (FL)
Lankford	Rigell	Young (IN)
Larsen (WA)		

NAYS—34

Amash	Campbell	Fincher
Bishop (UT)	Canseco	Flores
Brady (TX)	Carter	Fox
Broun (GA)	Conaway	Garrett
Camp	Culberson	Gingrey (GA)

Gohmert	Poe (TX)	Thompson (PA)
Granger	Pompeo	Thornberry
Huizenga (MI)	Posey	Webster
Long	Quayle	Westmoreland
McClintock	Rooney	Young (AK)
Neugebauer	Sessions	
Pearce	Stearns	

ANSWERED “PRESENT”—1

Ribble

NOT VOTING—11

Bachus	Lewis (CA)	Sánchez, Linda
Bass (CA)	Miller (FL)	T.
Dreier	Miller, Gary	Schock
Jackson (IL)	Reed	Walsh (IL)

## ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

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

□ 1422

Mr. GINGREY of Georgia changed his vote from “yea” to “nay.”

So the motion to instruct was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

# NOTICE OF INTENTION TO OFFER MOTION TO INSTRUCT CONFEREES ON H.R. 4348, SURFACE TRANSPORTATION EXTENSION ACT OF 2012, PART II

Mr. HOYER. Mr. Speaker, pursuant to clause 7(c) of rule XXII, I hereby give notice of my intention to offer a motion to instruct conferees on H.R. 4348.

The form of the motion is as follows:

Mr. HOYER moves that the managers on the part of the House at the conference on the disagreeing votes of the two Houses on the Senate amendment to the bill H.R. 4348 be instructed to recede from disagreement to the amendment of the Senate.

# NOTICE OF INTENTION TO OFFER MOTION TO INSTRUCT CONFEREES ON H.R. 4348, SURFACE TRANSPORTATION EXTENSION ACT OF 2012, PART II

Mrs. BLACK. Mr. Speaker, pursuant to rule XXII, clause 7(c), I hereby announce my intention to offer a motion to instruct on H.R. 4348.

The form of the motion is as follows:

Mrs. BLACK moves that the managers on the part of the House at the conference on the disagreeing votes of the two Houses on the Senate amendment to the bill H.R. 4348 be instructed to reject section 31108 of the Senate amendment (relating to distracted driving grants), other than the matter proposed to be inserted as section 411(g) of title 23, United States Code (relating to a distracted driving study).

# ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. WESTMORELAND). Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on the motion to suspend the rules on which a recorded vote or the yeas and nays are

ordered, or on which the vote incurs objection under clause 6 of rule XX.

Any record vote on the postponed question will be taken later.

## FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

Mr. UPTON. Mr. Speaker, I move to suspend the rules and pass the bill (S. 3187) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the amendment is as follows:

Amendment:

Strike out all after the enacting clause and insert:

### SECTION 1. SHORT TITLE.

This Act may be cited as the “Food and Drug Administration Safety and Innovation Act”.

### SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

(a) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents; references in Act.

#### TITLE I—FEES RELATING TO DRUGS

Sec. 101. Short title; finding.

Sec. 102. Definitions.

Sec. 103. Authority to assess and use drug fees.

Sec. 104. Reauthorization; reporting requirements.

Sec. 105. Sunset dates.

Sec. 106. Effective date.

Sec. 107. Savings clause.

#### TITLE II—FEES RELATING TO DEVICES

Sec. 201. Short title; findings.

Sec. 202. Definitions.

Sec. 203. Authority to assess and use device fees.

Sec. 204. Reauthorization; reporting requirements.

Sec. 205. Savings clause.

Sec. 206. Effective date.

Sec. 207. Sunset clause.

Sec. 208. Streamlined hiring authority to support activities related to the process for the review of device applications.

#### TITLE III—FEES RELATING TO GENERIC DRUGS

Sec. 301. Short title.

Sec. 302. Authority to assess and use human generic drug fees.

Sec. 303. Reauthorization; reporting requirements.

Sec. 304. Sunset dates.

Sec. 305. Effective date.

Sec. 306. Amendment with respect to misbranding.

Sec. 307. Streamlined hiring authority to support activities related to human generic drugs.

Sec. 308. Additional reporting requirements.

#### TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Sec. 401. Short title; finding.

Sec. 402. Fees relating to biosimilar biological products.

Sec. 403. Reauthorization; reporting requirements.

Sec. 404. Sunset dates.

Sec. 405. Effective date.

Sec. 406. Savings clause.

Sec. 407. Conforming amendment.

Sec. 408. Additional reporting requirements.

#### TITLE V—PEDIATRIC DRUGS AND DEVICES

Sec. 501. Permanence.

Sec. 502. Written requests.

Sec. 503. Communication with Pediatric Review Committee.

Sec. 504. Access to data.

Sec. 505. Ensuring the completion of pediatric studies.

Sec. 506. Pediatric study plans.

Sec. 507. Reauthorizations.

Sec. 508. Report.

Sec. 509. Technical amendments.

Sec. 510. Pediatric rare diseases.

Sec. 511. Staff of Office of Pediatric Therapeutics.

#### TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Sec. 601. Investigational device exemptions.

Sec. 602. Clarification of least burdensome standard.

Sec. 603. Agency documentation and review of significant decisions.

Sec. 604. Device modifications requiring pre-market notification prior to marketing.

Sec. 605. Program to improve the device recall system.

Sec. 606. Clinical holds on investigational device exemptions.

Sec. 607. Modification of de novo application process.

Sec. 608. Reclassification procedures.

Sec. 609. Harmonization of device premarket review, inspection, and labeling symbols.

Sec. 610. Participation in international fora.

Sec. 611. Reauthorization of third-party review.

Sec. 612. Reauthorization of third-party inspection.

Sec. 613. Humanitarian device exemptions.

Sec. 614. Unique device identifier.

Sec. 615. Sentinel.

Sec. 616. Postmarket surveillance.

Sec. 617. Custom devices.

Sec. 618. Health information technology.

Sec. 619. Good guidance practices relating to devices.

Sec. 620. Pediatric device consortia.

#### TITLE VII—DRUG SUPPLY CHAIN

Sec. 701. Registration of domestic drug establishments.

Sec. 702. Registration of foreign establishments.

Sec. 703. Identification of drug excipient information with product listing.

Sec. 704. Electronic system for registration and listing.

Sec. 705. Risk-based inspection frequency.

Sec. 706. Records for inspection.

Sec. 707. Prohibition against delaying, denying, limiting, or refusing inspection.

Sec. 708. Destruction of adulterated, misbranded, or counterfeit drugs offered for import.

Sec. 709. Administrative detention.

Sec. 710. Exchange of information.

Sec. 711. Enhancing the safety and quality of the drug supply.

Sec. 712. Recognition of foreign government inspections.

Sec. 713. Standards for admission of imported drugs.

Sec. 714. Registration of commercial importers.

Sec. 715. Notification.

Sec. 716. Protection against intentional adulteration.

Sec. 717. Penalties for counterfeiting drugs.

Sec. 718. Extraterritorial jurisdiction.

#### TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

Sec. 801. Extension of exclusivity period for drugs.

Sec. 802. Priority review.

Sec. 803. Fast track product.

Sec. 804. Clinical trials.

Sec. 805. Reassessment of qualified infectious disease product incentives in 5 years.

Sec. 806. Guidance on pathogen-focused antibacterial drug development.

#### TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

Sec. 901. Enhancement of accelerated patient access to new medical treatments.

Sec. 902. Breakthrough therapies.

Sec. 903. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.

Sec. 904. Accessibility of information on prescription drug container labels by visually impaired and blind consumers.

Sec. 905. Risk-benefit framework.

Sec. 906. Grants and Contracts for the Development of Orphan Drugs.

Sec. 907. Reporting of inclusion of demographic subgroups in clinical trials and data analysis in applications for drugs, biologics, and devices.

Sec. 908. Rare pediatric disease priority review voucher incentive program.

#### TITLE X—DRUG SHORTAGES

Sec. 1001. Discontinuance or interruption in the production of life-saving drugs.

Sec. 1002. Annual reporting on drug shortages.

Sec. 1003. Coordination; task force and strategic plan.

Sec. 1004. Drug shortage list.

Sec. 1005. Quotas applicable to drugs in shortage.

Sec. 1006. Attorney General report on drug shortages.

Sec. 1007. Hospital repackaging of drugs in shortage.

Sec. 1008. Study on drug shortages.

#### TITLE XI—OTHER PROVISIONS

##### Subtitle A—Reauthorizations

Sec. 1101. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.

Sec. 1102. Reauthorization of the critical path public-private partnerships.

##### Subtitle B—Medical Gas Product Regulation

Sec. 1111. Regulation of medical gases.

Sec. 1112. Changes to regulations.

Sec. 1113. Rules of construction.

##### Subtitle C—Miscellaneous Provisions

Sec. 1121. Guidance document regarding product promotion using the Internet.

Sec. 1122. Combating prescription drug abuse.

Sec. 1123. Optimizing global clinical trials.

Sec. 1124. Advancing regulatory science to promote public health innovation.

Sec. 1125. Information technology.

Sec. 1126. Nanotechnology.

Sec. 1127. Online pharmacy report to Congress.

Sec. 1128. Report on small businesses.

Sec. 1129. Protections for the commissioned corps of the public health service act.

Sec. 1130. Compliance date for rule relating to sunscreen drug products for over-the-counter human use.

Sec. 1131. Strategic integrated management plan.

Sec. 1132. Assessment and modification of REMS.

Sec. 1133. Extension of period for first applicant to obtain tentative approval without forfeiting 180-day-exclusivity period.

Sec. 1134. Deadline for determination on certain petitions.

Sec. 1135. Final agency action relating to petitions and civil actions.

Sec. 1136. Electronic submission of applications.

Sec. 1137. Patient participation in medical product discussions.

Sec. 1138. Ensuring adequate information regarding pharmaceuticals for all populations, particularly underrepresented subpopulations, including racial subgroups.