

“(C) as applicable—

“(i) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug; or

“(ii) the 1-year period referred to in section 351(k)(6)(A) of the Public Health Service Act as it applies to such biosimilar biological product application or to any other biosimilar biological product application based on the same brand name drug.”; and

(B) in subsection (b)—

(i) by amending paragraph (1) to read as follows:

“(1) REQUIREMENT.—

“(A) GENERIC DRUGS.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

“(B) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biosimilar biological product applicant that has submitted a biosimilar biological product application for which a statement under section 351(l)(3)(B)(ii)(I) of the Public Health Service Act has been provided with respect to a reference product and another biosimilar biological product applicant that has submitted a biosimilar biological product application for which such a statement for the same reference product has been provided shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the biosimilar biological products for which such biosimilar biological product applications were submitted.”; and

(ii) in paragraph (2)—

(I) by striking “between two generic drug applicants is an agreement” and inserting “is, as applicable, an agreement between 2 generic drug applicants”; and

(II) by inserting “, or an agreement between 2 biosimilar biological product applicants regarding the 1-year period referred to in section 351(k)(6)(A) of the Public Health Service Act as it applies to the biosimilar biological product applications with which the agreement is concerned” before the period;

(3) in section 1115, by striking “or generic drug applicant” each place such term appears and inserting “, generic drug applicant, or biosimilar biological product applicant”; and

(4) in section 1117, by striking “, or any agreement between generic drug applicants” and inserting “or a biosimilar biological product applicant, any agreement between generic drug applicants, or any agreement between biosimilar biological product applicants”.

Mr. ALEXANDER. Mr. President, the next vote is on Senator COLLINS' amendment on the gag rule with Senator MCCASKILL.

Following that, we will vote on the Opioid Crisis Act of 2018, which has the contributions of 72 Senators.

I would like to especially thank Senator MCCONNELL and Senator SCHUMER for creating an environment in which we could get this done.

Mr. President, I ask unanimous consent that the votes following the first vote in this series be 10 minutes in length.

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

The clerk will read the title of the bill for the third time.

The bill, as amended, was ordered to be engrossed for a third reading and was read the third time.

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall the bill pass?

Mr. ALEXANDER. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The clerk will call the roll.

The assistant bill clerk called the roll.

The result was announced—yeas 98, nays 2, as follows:

[Rollcall Vote No. 209 Leg.]

YEAS—98

Alexander	Gardner	Murray
Baldwin	Gillibrand	Nelson
Barrasso	Graham	Perdue
Bennet	Grassley	Peters
Blumenthal	Harris	Portman
Blunt	Hassan	Reed
Booker	Hatch	Risch
Boozman	Heinrich	Roberts
Brown	Heitkamp	Rounds
Burr	Heller	Rubio
Cantwell	Hirono	Sanders
Capito	Hoeven	Sasse
Cardin	Hyde-Smith	Schatz
Carper	Inhofe	Schumer
Casey	Isakson	Scott
Cassidy	Johnson	Shaheen
Collins	Jones	Shelby
Coons	Kaine	Smith
Corker	Kennedy	Stabenow
Cornyn	King	Sullivan
Cortez Masto	Klobuchar	Tester
Cotton	Kyl	Thune
Crapo	Lankford	Tillis
Cruz	Leahy	Toomey
Daines	Manchin	Udall
Donnelly	Markey	Van Hollen
Duckworth	McCaskill	Warner
Durbin	McConnell	Warren
Enzi	Menendez	Whitehouse
Ernst	Merkley	Wicker
Feinstein	Moran	Wyden
Fischer	Murkowski	Young
Flake	Murphy	

NAYS—2

Lee

Paul

The bill (S. 2554), as amended, was passed.

#### SUBSTANCE USE-DISORDER PREVENTION THAT PROMOTES OPIOID RECOVERY AND TREATMENT FOR PATIENTS AND COMMUNITIES ACT

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of H.R. 6.

The Senator from Ohio.

AMENDMENT NO. 4013

Mr. PORTMAN. Mr. President, I call up amendment No. 4013 and ask unanimous consent that it be reported by number.

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

The clerk will report the amendment by number.

The assistant bill clerk read as follows:

The Senator from Ohio [Mr. PORTMAN], for Mr. ALEXANDER, proposes an amendment numbered 4013.

Mr. PORTMAN. I ask unanimous consent that the reading of the amendment be dispensed with.

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

(The amendment is printed in the RECORD of September 6, 2018, under “Text of Amendments.”)

The PRESIDING OFFICER. Under the previous order, the amendment is agreed to.

The amendment was ordered to be engrossed and the bill to be read a third time.

The bill was read the third time.

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall the bill pass?

Mr. CARDIN. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The clerk will call the roll.

The senior assistant legislative clerk called the roll.

The result was announced—yeas 99, nays 1, as follows:

[Rollcall Vote No. 210 Leg.]

YEAS—99

Alexander	Gardner	Murray
Baldwin	Gillibrand	Nelson
Barrasso	Graham	Paul
Bennet	Grassley	Perdue
Blumenthal	Harris	Peters
Blunt	Hassan	Portman
Booker	Hatch	Reed
Boozman	Heinrich	Risch
Brown	Heitkamp	Roberts
Burr	Heller	Rounds
Cantwell	Hirono	Rubio
Capito	Hoeven	Sanders
Cardin	Hyde-Smith	Sasse
Carper	Inhofe	Schatz
Casey	Isakson	Schumer
Cassidy	Johnson	Scott
Collins	Jones	Shaheen
Coons	Kaine	Shelby
Corker	Kennedy	Smith
Cornyn	King	Stabenow
Cortez Masto	Klobuchar	Sullivan
Cotton	Kyl	Tester
Crapo	Lankford	Thune
Cruz	Leahy	Tillis
Daines	Manchin	Toomey
Donnelly	Markey	Udall
Duckworth	McCaskill	Van Hollen
Durbin	McConnell	Warner
Enzi	Menendez	Warren
Ernst	Merkley	Whitehouse
Feinstein	Moran	Wicker
Fischer	Murkowski	Wyden
Flake	Murphy	Young

NAYS—1

Lee

The bill (H.R. 6), as amended, was passed.

The PRESIDING OFFICER. The Senate majority leader.

#### DEPARTMENT OF DEFENSE AND LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION APPROPRIATIONS ACT, 2019—CONFERENCE REPORT

Mr. MCCONNELL. Mr. President, I ask that the Chair lay before the Senate the conference report to accompany H.R. 6157.

The PRESIDING OFFICER. The Chair lays before the Senate the conference report to accompany H.R. 6157, which the clerk will report by title.

The senior assistant legislative clerk read as follows: