TAM17975 S.L.C.

Lamar Alexander

#1

AMENDMENT NO._____ Calendar No._____

Purpose: To require certification from the Secretary prior to importation of prescription drugs.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by ____Alexander

Viz:

At the end of title VI, insert the following:

SEC. 6___. IMPORTATION REQUIREMENT.

Notwithstanding any other provision of law, importation of prescription drugs pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) shall be allowed only with certification from the Secretary of Health and Human Services that the prescription drug imported from outside of the United States will—

(1) pose no additional risk to the public's health and safety as compared to drugs approved under such Act;

(2) not increase the public's exposure to counterfeit drugs; and

(3) not further exacerbate the nationwide opioid abuse crisis.

Bennet—S. 934—Amendment #1

AMENDMENT NO._____ Calendar No._____

Purpose: To amend the Federal Food, Drug, and Cosmetic Act to establish a program to increase the development of new drugs to treat pediatric cancers, and for other purposes.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. BENNET

Viz:

At the end of title V, add the following:

SEC. 505. DRUG DEVELOPMENT FOR PEDIATRIC CANCER.

(a) MOLECULAR TARGETS REGARDING CANCER DRUGS.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) in subsection (a)(2)(A)(i) by striking "product for the claimed indications in all relevant pediatric subpopulations; and" and inserting "product in all relevant pediatric subpopulations—

"(I) for the claimed indications; or".

"(II) for a pediatric cancer indication, if the drug is intended for the treatment of an adult cancer and is directed at a molecular target considered to be germane to the growth and progression of such pediatric cancer; and";

(2) in subsection (b)(1)—

(A) by amending subparagraph (A)(i) to read as follows:

"(A)(i) the drug or biological product is used for a substantial number of pediatric patients—

"(I) for the labeled indications; or

"(II) for a pediatric cancer indication, if the drug is intended for the treatment of an adult cancer and is directed at a molecular target considered to be germane to the growth and progression of such pediatric cancer; and"; and

(B) by amending subparagraph (B) to read as follows:

"(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients—

"(i) for 1 or more of the claimed indications; or

"(ii) for a pediatric cancer indication, if the drug is intended for the treatment of an adult cancer and is directed at a molecular target considered to be germane to the growth and progression of such pediatric cancer; or"; and

(3) by amending paragraph (2) of subsection (c) to read as follows:

"(2) the drug or biological product is in a class of products, is for an indication, or is directed at a specific molecular target in an adult cancer and such molecular target is germane to the growth or progression of cancer in a pediatric cancer, for which there is need for additional options.".

(b) EARLY MEETING ON PEDIATRIC STUDY PLAN.—

(1) IN GENERAL.—Clause (i) of section 505B(e)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)(2)(C)) is amended to read as follows:

"(i) shall meet with the applicant—

"(I) if requested by the applicant with respect to a drug that is intended to treat a serious or life-threatening disease or condition, to discuss preparation of the initial pediatric study plan, not later than the end-of-Phase 1 meeting (as such term is used in section 312.47(b) of title 21, Code of Federal Regulations, or successor regulations) or within 30 days of receipt of such request, whichever is later;

"(II) to discuss the initial pediatric study plan as soon as practicable, but not later than 90 calendar days after the receipt of such plan under subparagraph (A); and

"(III) to discuss any scientific or operational challenges that may be the basis of a deferral under subsection (a)(3) or a full or partial waiver under subsection (a)(4);".

(2) CONFORMING CHANGES.—Section 505B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(c)) is amended—

(A) in the heading of paragraph (2), by striking "MEETING" and inserting "MEETINGS";

(B) in the heading of paragraph (2)(C), by striking "MEETING" and inserting "MEETINGS";

(C) in clauses (ii) and (iii) of paragraph (2)(C), by striking "no meeting" each place it appears and inserting "no meeting under clause (i)(II)"; and

(D) in paragraph (3) by striking "meeting under paragraph (2)(C)(i)" and inserting "meeting under paragraph (2)(C)(i)(II)".

(c) ORPHAN DRUGS.—Section 505B(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(k)) is amended by inserting "except in the case of a drug or biological product that is intended for the treatment of an adult cancer and is directed at a molecular target considered to be germane to the growth and progression of a pediatric cancer," after "regulation,".

(d) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of

Food and Drugs, shall issue guidance on the implementation of the amendments to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) made by this section, including—

(1) study designs;

(2) molecular targets considered to be germane to the growth and progression present in one or more cancers in pediatric populations that may be appropriate for assessment under such section 505B, as so amended; and

(3) considerations for implementation of such section 505B, as so amended, and waivers of the requirements of such section 505B with regard to molecular targets for which several drugs may be under investigation.

(e) APPLICABILITY.—This section and the amendments made by this section apply with respect to applications for a drug submitted under section 505 of the Federal Food, Drug, or Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) on or after the date that is 18 months after the date of enactment of this Act.

(f) REPORT TO CONGRESS.—Section 508(b) of the FDA Safety and Innovation Act (21 U.S.C. 355c–1(b)) is amended—

(1) in paragraph (10), by striking "; and" and inserting ";"; and

(2) by striking paragraph (11) and inserting the following:

"(11) an assessment of the impact of the amendments to such section 505B made by the FDA Authorization Act of 2017 on pediatric labeling of drugs and pediatric labeling of molecularly targeted drugs for the treatment of cancer;

"(12) an assessment of the efforts of the Secretary to implement the plan developed under section 505C–1 of the Federal Food, Drug, and Cosmetic Act, regarding earlier submission of pediatric studies under sections 505A and 505B, including—

"(A) the average length of time after the approval of an application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) before studies conducted pursuant to such sections 505A or 505B are completed, submitted, and incorporated into labeling;

"(B) the average length of time after the receipt of a proposed pediatric study request before the Secretary responds to such request;

"(C) the average length of time after the submission of a proposed pediatric study request before the Secretary issues a written request for such studies;

"(D) the number of written requests issued for each investigational new drug prior to the submission of an application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act; and

"(E) the average number, and range of numbers, of amendments to written requests issued;

"(13) a list of sponsors of applications or holders of approved applications who received exclusivity under such section 505A after receiving a letter issued under such section 505B(d)(1) and before the studies referred to in such letter were completed and submitted; and

"(14) a list of assessments required under subsection (a)(2)(A)(i)(II), and (b)(1)(B)(ii) of section 505B.".

(g) RULE OF CONSTRUCTION.—Nothing in this section, including the amendments made by this section, shall limit the authority of the Secretary of Health and Human Services to issue written requests under section 505A of

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a).

SEC. 506. IMPROVING THE TIMELINESS OF PEDIATRIC STUDIES.

(a) INFORMING INTERNAL REVIEW COMMITTEE.—Section 505A(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(f)) is amended by adding at the end the following:

"(7) INFORMING INTERNAL REVIEW COMMITTEE.—The Secretary shall provide to the committee referred to in paragraph (1) any response issued to an applicant or holder with respect to a proposed pediatric study request.".

(b) ACTION ON SUBMISSIONS.—Section 505A(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)) is amended—

(1) by redesignating paragraphs (3) through (5) as paragraphs (4) through (6), respectively; and

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

"(3) ACTION ON SUBMISSIONS.—The Secretary shall review and act upon a submission of a proposed pediatric study request or a sponsor's proposed amendment to a written request for pediatric studies within 120 days of the submission.".

(c) STUDY.—The Secretary of Health and Human Services, acting through the internal review committee established under section 505C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355d) shall, not later than one year after the date of enactment of this Act, develop and implement a plan to achieve, when appropriate, earlier submission of pediatric studies under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Such plan shall include recommendations to achieve—

(1) earlier discussion of proposed pediatric study requests and written requests with sponsors, and if appropriate, at the meeting required under section 505B(e)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)(2)(C)), as amended by section 505 of this Act;

(2) earlier issuance of written requests for a pediatric study under such section 505A, including for investigational new drugs prior to the submission of an application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)); and

(3) shorter timelines, when appropriate, for the completion of studies pursuant to a written request under such section 505A.

SEC. 507. NEONATOLOGY EXPERTISE.

Section 6(d) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(d)) is amended by striking "For the 5-year period beginning on the date of enactment of this subsection, at" and inserting "At".

Bennet_S. 934_ Amendment #2

AMENDMENT NO._____ Calendar No._____

Purpose: To increase the development of new drugs to treat pediatric cancers.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. BENNET

Viz:

At the end of title V, insert the following:

SEC. 505. DEVELOPMENT OF DRUGS AND BIOLOGICAL PRODUCTS FOR PEDIATRIC CANCERS.

(a) MOLECULAR TARGETS REGARDING CANCER DRUGS.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) in subsection (a)—

(A) in paragraph (2)(A)(i) by striking "product for the claimed indications in all relevant pediatric subpopulations; and" and in-

serting "product in all relevant pediatric subpopulations—

"(I) for the claimed indications; or".

"(II) for one pediatric cancer indication, if the drug or biological product is—

"(aa) the subject of an original application that is submitted not less than 2 years after the date of enactment of the FDA Reauthorization Act of 2017;

"(bb) intended for the treatment of an adult cancer;

"(cc) determined by scientific evidence to be directed at a molecular target, on the basis of data the Secretary determines to be adequate, to be germane to the development or growth of such pediatric cancer; and

"(dd) on the list under subsection (m) at the time of submission of such original application; and"; and

(B) by adding at the end the following:

"(5) RULE OF CONSTRUCTION.—Paragraphs (3) and (4) (regarding deferrals and waivers) apply to the same extent and in the same manner to assessments described in each of subclauses (I) and (II) of paragraph (2)(A)(i).";

(2) in subsection (b)—

(A) in paragraph (1)—

(i) by amending subparagraph (A)(i) to read as follows:

"(A)(i) the drug or biological product is used for a substantial number of pediatric patients—

"(I) for the labeled indications; or

"(II) for one pediatric cancer indication, if the drug or biological product is—

"(aa) the subject of an original application that is submitted not less than 2 years after the date of enactment of the FDA Reauthorization Act of 2017;

"(bb) intended for the treatment of an adult cancer; and

"(cc) determined by scientific evidence to be directed at a molecular

target, on the basis of data the Secretary determines to be adequate, to be germane to the development or growth of such pediatric cancer; and

"(dd) on the list under subsection (m) at the time of submission of such original application; and"; and

(ii) by amending subparagraph (B) to read as follows:

"(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients—

"(i) for 1 or more of the claimed indications; or

"(ii) for one pediatric cancer indication, if the drug or biological product is—

"(I) the subject of an original application that is submitted not less than 2 years after the date of enactment of the FDA Reauthorization Act of 2017;

"(II) intended for the treatment of an adult cancer;

"(III) determined by scientific evidence to be directed at a molecular target, on the basis of data the Secretary determines to be adequate, to be germane to the development or growth of such pediatric cancer; and

"(IV) on the list under subsection (m) at the time of submission of such original application; or"; and

(B) by adding at the end the following:

"(4) RULE OF CONSTRUCTION.—Paragraph (2) (regarding waivers) applies to the same extent and in the same manner to assessments required under each of subclauses (I) and (II) of paragraph (1)(A)(i) and assessments required under each of clauses (i) and (ii) of paragraph (1)(B), respectively.";

(3) by amending paragraph (2) of subsection (e) to read as follows:

"(2) the drug or biological product is in a class of products, is for an indication, or is directed at a specific molecular target in an adult cancer and such molecular target is germane to the growth or progression of cancer in a pediatric cancer, for which there is need for additional options."; and

(4) by adding at the end the following:

"(m) LIST OF PRIMARY MOLECULAR TARGETS.—

"(1) IN GENERAL.—Within one year of the date of enactment of the FDA Reauthorization Act of 2017, the Secretary shall establish and update regularly a list of molecular targets considered, on the basis of data the Secretary determines to be adequate, to be germane to the growth and progression of a pediatric cancer, and shall publish such list in the Federal Register.

"(2) CONSULTATION.—In establishing the list described in paragraph (1), the Secretary shall—

"(A) consult members of the internal committee under section 505C and the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; and

"(B) convene a public meeting not later than 1 year after the date of enactment of the FDA Reauthorization Act of 2017 to solicit stakeholder comment on the appropriate contents of such list and the data necessary to determine that there is scientific evidence that a drug or biological product is directed at a molecular target that is considered, on the basis of data the Secretary determines to be adequate,

to be germane to the growth or progression of a pediatric cancer.".

(b) ORPHAN DRUGS.—Section 505B(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(k)) is amended to read as follows:

"(k) RELATION TO ORPHAN DRUGS.—

"(1) IN GENERAL; EXEMPTION FOR ORPHAN INDICATIONS.—Unless the Secretary requires otherwise by regulation, except as provided under paragraph (2), this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.

"(2) APPLICABILITY DESPITE ORPHAN DESIGNATION OF CERTAIN CANCER INDICATIONS.—This section shall apply to a drug or biological product has been designated under section 526 for an indication for a pediatric or adult cancer if such drug or biological product is intended for the treatment of an adult cancer and is determined by scientific evidence to be directed at a molecular target that is considered, on the basis of data the Secretary determines to be adequate, to be germane to the growth or progression of a pediatric cancer.".

(c) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and

Human Services (referred to in this subsection as the "Secretary"), acting through the Commissioner of Food and Drugs and in consultation with the Pediatric Oncology Advisory Committee of the Food and Drug Administration, the Director of the National Cancer Institute, and other appropriately identified pediatric oncology experts from both the public and private sectors (including industry and academia), shall hold a public meeting, obtain public comment, and issue guidance on the implementation of the amendments to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) made by this section, including—

(1) the scientific criteria and regulatory considerations for determining by scientific evidence whether a drug or biological product indicated for the treatment of an adult cancer is directed at a molecular target germane to the growth or progression of a pediatric cancer;

(2) the scientific data, including clinical and preclinical evidence, needed to determine whether a molecular target is germane to the growth or progression of a pediatric cancer;

(3) the process the Secretary will use to make a determination described in paragraph (2);

(4) how the Secretary will collaborate with pediatric networks, academic centers, and experts in pediatric oncology to conduct pediatric cancer studies;

(5) processes to ensure requirements and timelines are aligned for assessments under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c);

(6) scientific and regulatory considerations for study designs, including the applicability of innovative regulatory science techniques for pediatric drug developments under such sections 505A and 505B; and

(7) considerations for implementation of such section 505B, as so amended, and waivers of the requirements of such section 505B with regard to molecular targets for which several drugs or biological products may be under investigation.

(d) REPORT TO CONGRESS.—Section 508(b) of the Food and Drug Administration Safety and Innovation Act (21 U.S.C. 355c–1(b)) is amended—

(1) in paragraph (10), by striking "; and" and inserting ";"; and

(2) by striking paragraph (11) and inserting the following:

"(11) an assessment of the impact of the amendments to such section 505B made by the on pediatric labeling of drugs and biological products and pediatric labeling of molecularly targeted drugs for the treatment of cancer;

"(12) an assessment of the efforts of the Secretary to implement the plan developed under section 505C–1 of the Federal Food, Drug, and Cosmetic Act, regarding earlier submission of pediatric studies under sections 505A and 505B of such Act and section 351(m) of the Public Health Service Act, including—

"(A) the average length of time after the approval of an application 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)) before studies conducted pursuant to such section 505A, 505B, or section 351(m) are completed, submitted, and incorporated into labeling;

"(B) the average length of time after the receipt of a proposed pediatric study request before the Secretary responds to such request;

"(C) the average length of time after the submission of a proposed pediatric study request before the Secretary issues a written request for such studies;

"(D) the number of written requests issued for each investigational new drug or biological product prior to the submission of an application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act; and

"(E) the average number, and range of numbers, of amendments to written requests issued;

"(13) a list of sponsors of applications or holders of approved applications who received exclusivity under such section 505A or such section 351(m) after receiving a letter issued under such section 505B(d)(1) and before the studies referred to in such letter were completed and submitted;

"(14) a list of assessments required under subsection (a)(2)(A)(i)(II), (b)(1)(A)(i)(II), and (b)(1)(B)(ii) of such section 505B; and

"(15) the Secretary's assessment of the overall impact of the amendments made by section 505 of the FDA Reauthorization Act of 2017 on the con-

duct and effectiveness of pediatric cancer research and the Secretary's subsequent recommendations, taking into account the report described in section 505(g) of the FDA Reauthorization Act of 2017.".

(e) RULE OF CONSTRUCTION.—Nothing in this section, including the amendments made by this section, shall limit the authority of the Secretary of Health and Human Services to issue written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) or section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)).

(f) PROVIDING CERTAINTY REGARDING PEDIATRIC STUDY PLANS.—Section 505B(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)) is amended—

(1) in paragraph (3)—

(A) by striking "Not later" and inserting the following:

"(A) IN GENERAL.—Not later"; and

(B) by adding at the end the following:

"(B) CHANGES TO AGREEMENT.—An agreement documented and confirmed as described in subparagraph (A) shall not be changed with respect to a specific agreed study after such study begins, except—

"(i) with the written agreement of the applicant; or

"(ii) pursuant to a written decision by the director of the reviewing division, that a substantial scientific issue essential to determining the adequacy of the pediatric assessments has been identified after such specific agreed study has begun, provided that the Secretary provides the applicant an opportunity for a meeting at which the director and the applicant will be present and at which the director will document the scientific issue involved."; and

(2) in paragraph (5), by striking the first sentence and inserting "Subject to paragraph (3), at the initiative of the Secretary or the applicant, the agreed initial pediatric study plan may be amended."; and

(3) in paragraph (6), by inserting "under paragraph (5)" before the period at the end.

(g) GAO REPORT.—

(1) IN GENERAL.—Beginning on the date that is 5 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of the effectiveness of requiring pe-

diatric assessments described in subsections (a)(2)(A)(i)(II), (b)(1)(A)(i)(II) and (b)(1)(B)(ii) of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c), as amended by this section, in the development of drugs and biological products for pediatric cancer indications. The Comptroller General shall examine—

(A) the indications studied in pediatric assessments required for drugs or biological products intended for the treatment of an adult cancer;

(B) the number of pediatric cancer indications for which assessments have been required under subsections (a)(2)(A)(i)(II), (b)(1)(A)(i)(II), and (b)(1)(B)(ii) of such section 505B;

(C) the number of requests for deferral and waiver of pediatric assessments required under such subsections and the number of such deferral and waiver requests granted and denied;

(D) the number of orphan-designated indications for drugs and biological products for which assessments were required under such subsections;

(E) the number of drugs and biological products approved for the treatment of cancer in the pediatric population for which the supportive studies were required to be conducted under such subsections; and

(F) any additional considerations by the Secretary regarding the effectiveness of requiring pediatric assessments described in subsections (a)(2)(A)(i)(II), (b)(1)(A)(i)(II) and (b)(1)(B)(ii) of such section 505B of the in the development of drugs and biological products for pediatric cancer indications.

(2) REPORT.—Not later than the date that is 6 years after the date of enactment of this Act, the Comptroller General of the United States shall submit a report containing the results of the study under paragraph (1) to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives.

Bill Cassidy, M.D.

TAM17982 S.L.C.

AMENDMENT NO. 1 Calendar No._____

Purpose: To direct the Secretary to issue guidance regarding the demonstration of bioequivalence.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. CASSIDY

Viz:

At the appropriate place, insert the following:

SEC. _____. GUIDANCE REGARDING BIOEQUIVALENCE.

(a) IN GENERAL.—In accordance with subsection (b), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue product-specific guidance, that—

(1) applies to complex non-biologic drugs; and

(2) outlines how to demonstrate bioequivalence to the reference drug in order to facilitate generic development for such drugs.

(b) DEADLINE FOR ISSUING GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a guidance for each complex non-biologic drug that is approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)). Such guidance shall be published not less than 2 years prior to the earliest date on which an abbreviated new drug application may be submitted pursuant to section 505(j) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) that refcrences such drug.

(c) APPLICABILITY.—This section applies to guidances whose deadline would be on or after October 1, 2017, based on subsection (b).

TAM17983 S.L.C. Susan M. Collins

AMENDMENT NO. 1 Calendar No._____

Purpose: To improve the bill.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. COLLINS (for herself and Mr. FRANKEN)

Viz:

At the end, add the following:

TITLE IX—GENERIC DRUG ACCESS

Subtitle A—Removing Regulatory Barriers to Competition

SEC. 901. IMPROVING ACCESS TO GENERIC DRUGS.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

"(11)(A) The Secretary shall prioritize the review of, and act within 240 calendar days of the date of the sub-

mission of, an original abbreviated new drug application submitted for review under this subsection, or on a supplement to such an application, that is for a drug—

"(i) for which there are not more than 3 approved drugs listed under paragraph (7), except that the review of an application submitted more than 30 months in advance of the last applicable expiration date for a patent for which a certification under paragraph (2)(A)(vii)(III) has been submitted, or of the expiration date for an applicable period of exclusivity under this Act, will not be expedited; or

"(ii) that has been included on the list under section 506E.

"(B) The Secretary shall require the applicant, not later than 60 days prior to the submission of an application described in subparagraph (A), to provide complete, accurate information regarding facilities involved in manufacturing processes and testing, including facilities in corresponding Type II active pharmaceutical ingredients drug master files submitted with an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, in order to make a determination regarding whether an inspection of an establishment is necessary.

"(C) The Secretary may expedite an inspection or re-inspection under section 704 of an establishment that proposes to manufacture a drug described in subparagraph (A).

"(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

"(12) The Secretary shall provide review status updates to applicants regarding applications under this subsection, as appropriate, including when the application is awaiting final regulatory action by the office charged with review.

"(13) The Secretary shall publish on the Internet website of the Food and Drug Administration a list of all drugs approved under subsection (b) for which all patents and periods of exclusivity under this Act have expired. Such list shall be updated at least once every 180 days.".

SEC. 902. REPORTING ON PENDING GENERIC DRUG APPLICATIONS, PRIORITY REVIEW APPLICATIONS, AND INSPECTIONS.

(a) IN GENERAL.—Not later than 180 calendar days after the date of enactment of this Act, and quarterly thereafter until October 1, 2022, the Secretary of Health and Human Services (referred to in this section as the

"Secretary") shall post on the Internet website of the Food and Drug Administration a report that provides—

(1) the number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) awaiting action by the applicant, including such applications that were filed prior to October 1, 2014;

(2) the number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) awaiting action by the Secretary, including such applications that were filed prior to October 1, 2014;

(3) the number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) and prior approval supplements withdrawn in each month covered by the report;

(4) the mean and median approval and tentative approval times for applications covered by the report;

(5) the number of applications described in paragraphs (1), (2), and (3) that are subject to priority review; and

(6) the number of such applications on which the Secretary has taken action pursuant to section

506H(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 901.

(b) ANNUAL REPORT ON PRIORITY REVIEW APPLICATIONS.—

(1) IN GENERAL.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Special Committee on Aging of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report, not later than March 31 of each year, on the following:

(A) The number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that are subject to priority review during the most recent calendar year and are awaiting action by the applicant.

(B) The number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that are subject to priority review during the most recent calendar year and are awaiting action by the Secretary.

(C) The number of applications filed under section 505(j) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355(j)) that are subject to priority review during the most recent calendar year and have been approved by the Secretary.

(D) For each of subparagraphs (A) through (C), the number of such applications—

(i) for which there are not more than 3 approved drugs listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(ii) the number of such applications that are for a drug on the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e).

(c) ANNUAL REPORT ON INSPECTIONS.—Not later than March 1 of each year, the Secretary shall post on the Internet website of the Food and Drug Administration—

(1) the average and median amount of time, following a request by staff of the Food and Drug Administration reviewing an application or report submitted under an applicable section described in subparagraph (A), (B), or (C), to schedule and complete inspections of facilities necessary for—

(A) approval of a drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) approval of a device under section 515 of such Act (21 U.S.C. 360e); and

(C) clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)); and

(2) the average and median amount of time to schedule and complete for-cause inspections of facilities of drugs and devices.

Subtitle B—Incentivizing Competition

SEC. 911. EXPEDITING GENERIC COMPETITION.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506G the following:

"SEC. 506H. EXPEDITING GENERIC DRUG DEVELOPMENT.

"(a) IN GENERAL.—The Secretary shall, at the request of an applicant, expedite the development and review of an application under subsection (j) of section 505 for a drug—

"(1) for which there are not more than 3 approved drug products listed under section 505(j)(7); or

"(2) that is included on the list under section 506E.

"(b) REQUEST FROM SPONSORS.—A request to expedite the development and review of an application under subsection (a) shall be submitted by the applicant prior to the submission of such application.

"(c) OTHER APPLICATIONS.—Nothing in this section shall prevent the Secretary from expediting the development and review of other applications as the Secretary determines appropriate.

"(d) ADDITIONAL COMMUNICATION.—The Secretary shall take such actions as are appropriate to expedite the development and review of the application for approval of a drug described in subsection (a), including, as appropriate—

"(1) holding meetings with the sponsor and the review team throughout the development of the drug prior to submission of the application;

"(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the application to ensure that the collection of nonclinical and clinical data necessary for approval is as efficient as practicable;

"(3) in the case of a complex product, assigning a cross-disciplinary project lead for the review team

to facilitate an efficient review of the development program and application, including manufacturing inspections; and

"(4) in the case of a complex product, including drug-device combinations, involving senior managers and experienced review staff, as appropriate, in a collaborative, cross- disciplinary review.

"(e) REPORTING REQUIREMENT.—A sponsor of a drug expedited under this section shall report to the Secretary, one year following approval of an application under section 505(j), on whether the approved drug has been marketed in interstate commerce since approval.".

SEC. 912. LIST OF GENERIC DRUGS WITH LIMITED COMPETITION.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506H, as added by section 911, the following:

"SEC. 506I. DRUG LISTING.

"(a) REMOVAL, WITHDRAWAL, OR TRANSFER.—The holder of an application approved under subsection (b) or (j) of section 505 shall notify the Secretary within 180 days of removing the drug that is the subject of such application from interstate commerce, withdrawing such approved application, or transferring such approved application, and a reason for such removal, withdrawal, or trans-

fer. If compliance with this subsection within such 180-day period is not practicable, then the holder shall comply as soon as practicable. The Secretary shall cross-reference information listed pursuant to section 506C where applicable to avoid duplicative reporting.

"(b) DRUGS WITH LIMITED COMPETITION.—

"(1) INFORMATION.—The Secretary shall—

"(A) maintain information with respect to applications approved under section 505(j); and

"(B) publish on the Internet website of the Food and Drug Administration such information under subparagraph (A) with respect to drugs for which there are 3 or fewer application holders; and

"(C) update the information published pursuant to subparagraph (B) every 180 days.

"(2) CONTENTS.—The public information maintained and published under paragraph (1)(B) shall include—

"(A) the name of the drug, name of the holder of the approved application, and the marketing status for each drug; and

"(B) an indication of whether the Secretary considers the drug to be for the treatment or prevention of a serious disease or med-

ical condition, for which there is no alternative drug that is judged by medical professionals to be an adequate substitute available in adequate supply.

"(c) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available if the Secretary determines that disclosure of such information would adversely affect the public health.

"(d) NOTIFICATION.—When the Secretary first publishes the information under subsection (b), the Secretary shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, that the information has been published and will be updated regularly.".

SEC. 913. SUITABILITY PETITIONS.

(a) IN GENERAL.—It is the sense of the Senate that the Food and Drug Administration shall meet the requirement under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(C)) and section 314.93(e) of title 21, Code of Federal Regulations, of responding to suitability petitions within 90 days of submission.

(b) REPORT.—The Secretary of Health and Human Services shall include in the annual reports under section 902(b)—

(1) the number of pending petitions under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(C)); and

(2) the number of such petitions pending a substantive response for more than 180 days from the date of receipt.

SEC. 914. INSPECTIONS.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), as amended by section 901, is further amended by adding at the end the following:

"(14) If the Secretary issues feedback pursuant to section 704(b)(2) with respect to information submitted in response to a report under section 704(b)(1), and a report that was issued under section 704(b)(1) is the only obstacle to approval of an application under this subsection or the Secretary determines that the public health benefit of approving an application under this subsection outweighs any risk to public health, the Secretary shall, within 45 days of notification by the applicant that necessary changes have been made to the establishment to address any findings or deficiencies identified previously by the Secretary—

"(A) re-inspect the establishment with respect to which the report was issued; or

"(B) make a determination regarding the response to such report and review of such application.".

Hatch

AMENDMENT NO. 1 Calendar No._____

Purpose: To expand patient access to experimental treatments in clinical trials, and for other purposes.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. HATCH (for himself, Mr. BENNET, Mr. BURR, and Mr. CASEY)

Viz:

At the appropriate place, insert the following:

SEC. ___. EXPANDED ACCESS.

(a) PATIENT ACCESS TO EXPERIMENTAL TREATMENTS.—

(1) PUBLIC MEETING.—

(A) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, in coordination with the Director of the National Institutes

of Health, and in consultation with patients, health care providers, drug sponsors, bioethicists, and other stakeholders, shall, not later than 180 days after the date of enactment of this Act, convene a public meeting to discuss clinical trial inclusion and exclusion criteria to inform the guidance under paragraph (3). The Secretary shall inform the Comptroller General of the United States of the date when the public meeting will take place.

(B) TOPICS.—The Secretary shall provide a publicly available report on the topics discussed at the meeting described in subparagraph (A) within 30 days of such meeting. Such topics shall include discussion of—

(i) the rationale for, and potential barriers for patients created by, clinical trial inclusion and exclusion criteria;

(ii) how patient populations most likely to be affected by a drug can benefit from the results of trials that employ alternative designs, as well as potential risks associated with alternative clinical trial designs;

(iii) barriers to participation in clinical trials, including—

(I) information regarding any potential risks and benefits of participation;

(II) regulatory, geographical, and socioeconomic barriers; and

(III) the impact of exclusion criteria on the enrollment in clinical trials of infants and children, pregnant and lactating women, seniors, individuals with advanced disease, and individuals with co-morbid conditions;

(iv) clinical trial designs and methods that increase enrollment of more diverse patient populations while facilitating the collection of data to support substantial evidence of safety and effectiveness; and

(v) how changes to clinical trial inclusion and exclusion criteria may impact the complexity of the clinical trial design and length of clinical trials, and potential approaches to mitigating those impacts to ensure that the ability to demonstrate safety

and effectiveness is not hindered through potential changes in eligibility criteria.

(2) REPORT.—Not later than 1 year after the Secretary issues a report on the topics discussed at the public meeting under paragraph (1)(B), the Comptroller General of the United States shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on individual access to investigational drugs through the expanded access program under section 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)). The report shall include—

(A) a description of actions taken by manufacturers under section 561A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0);

(B) consideration of whether Form FDA 3926 and the guidance document entitled "Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers", issued by the Food and Drug Administration in June 2016, has reduced application burden with respect to individuals and physicians seeking access to investigational new drugs pursu-

ant to section 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) and improved clarity for patients, physicians, and drug manufacturers about such process;

(C) consideration of whether the guidance or regulations released or updated under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) have improved access for individual patients who do not qualify for clinical trials of such investigational drugs, and what barriers to such access remain;

(D) an assessment of how patients and health care providers navigate different avenues to engage with the Food and Drug Administration or drug sponsors on expanded access; and

(E) an analysis of the Secretary's report under paragraph (1)(B).

(3) GUIDANCE.—

(A) IN GENERAL.—Not later than 180 days after the publication of the report under paragraph (1), the Secretary, acting through the Commissioner of Food and Drugs, shall issue one or more draft guidances regarding eligibility criteria for clinical trials. Not later than 18 months after the public comment period on

each such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(B) CONTENTS.—The guidance documents described in subparagraph (A) shall address methodological approaches that a manufacturer or sponsor of an investigation of a new drug may take to—

(i) broaden eligibility criteria for clinical trials, especially with respect to drugs for the treatment of serious and life-threatening conditions or diseases for which there is an unmet medical need; and

(ii) develop eligibility criteria for, and increase trial recruitment to, clinical trials so that enrollment in such trials more accurately reflects the patients most likely to receive the drug, as applicable and as appropriate, while supporting findings of substantial evidence of safety and effectiveness.

(b) IMPROVING INSTITUTIONAL REVIEW BOARD REVIEW OF SINGLE PATIENT EXPANDED ACCESS PROTOCOL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commis-

sioner of Food and Drugs, shall issue guidance or regulations, or revise existing guidance or regulations, to streamline the institutional review board review for individual pediatric and adult patient expanded access protocol under 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)). Such guidance or regulation may include a description of the conditions under which an institutional review board chair (or designee) may review individual patient expanded access protocol submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) for a drug and how centralized institutional review boards may facilitate the use of expanded access protocols. The Secretary shall update any relevant forms associated with individual patient expanded access protocol as necessary.

(c) EXPANDED ACCESS POLICY TRANSPARENCY.—Section 561A(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0(f)) is amended—

(1) in the matter preceding paragraph (1), by striking "later" and inserting "earlier";

(2) by striking paragraph (1);

(3) by redesignating paragraph (2) as paragraph (1);

(4) in paragraph (1) as so redesignated, by striking the period at the end and inserting "; or"; and

(5) by adding at the end the following:

"(2) as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy under subsection (a), (b), or (g), respectively, of section 506.".

Hatch

AMENDMENT NO. 2 Calendar No._____

Purpose: To authorize an extension of exclusivity periods for certain drugs that are approved for a new indication for a rare disease or condition, and for other purposes.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. HATCH

Viz:

At the appropriate place, insert the following:

SEC. ___. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505F of such Act (21 U.S.C. 355g) the following:

"SEC. 505G. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

"(a) DESIGNATION.—

"(1) IN GENERAL.—The Secretary shall designate a drug as a drug approved for a new indication to prevent, diagnose, or treat a rare disease or condition for purposes of granting the extensions under subsection (b) if—

"(A) prior to approval of an application or supplemental application for the new indication, the drug was approved or licensed under section 505(c) of this Act or section 351(a) of the Public Health Service Act but was not so approved or licensed for the new indication;

"(B)(i) the sponsor of the approved or licensed drug files an application or a supplemental application for approval of the new indication for use of the drug to prevent, diagnose, or treat the rare disease or condition; and

"(ii) the Secretary approves the application or supplemental application; and

"(C) the application or supplemental application for the new indication contains the consent of the applicant to public notice under

paragraph (3) with respect to the designation of the drug.

"(2) REVOCATION OF DESIGNATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), a designation under paragraph (1) shall not be revoked for any reason.

"(B) EXCEPTION.—The Secretary may revoke a designation of a drug under paragraph (1) if the Secretary finds that the application or supplemental application resulting in such designation contained an untrue statement of material fact.

"(3) NOTICE TO PUBLIC.—The Secretary shall provide public notice of the designation of a drug under paragraph (1).

"(b) EXTENSION.—

"(1) IN GENERAL.—If the Secretary designates a drug as a drug approved for a new indication for a rare disease or condition, as described in subsection (a)(1)—

"(A)(i) the 4-, 5-, and 7½-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection

(j)(5)(F) of section 505, and the 7-year period described in section 527, as applicable, shall be extended by 6 months; or

"(ii) the 4- and 12-year periods described in subparagraphs (A) and (B) of section 351(k)(7) of the Public Health Service Act and the 7-year period described in section 527, as applicable, shall be extended by 6 months; and

"(B)(i) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 or a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or

"(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the

certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions).

"(2) RELATION TO PEDIATRIC AND QUALIFIED INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any extension under paragraph (1) of a period shall be in addition to any extension of the periods under sections 505A and 505E of this Act and section 351(m) of the Public Health Service Act, as applicable, with respect to the drug.

"(c) LIMITATIONS.—Any extension described in subsection (b)(1) shall not apply if the drug designated under subsection (a)(1) has previously received an extension by operation of subsection (b)(1).

"(d) DEFINITION.—In this section, the term 'rare disease or condition' has the meaning given to such term in section 526(a)(2).".

(b) APPLICATION.—Section 505G of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug for which an application or supplemental application described in subsection

(a)(1)(B)(i) of such section 505G is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) between the date of enactment of this Act and the date that is 7 years after such date of enactment.

(c) CONFORMING AMENDMENTS.—

(1) RELATION TO PEDIATRIC EXCLUSIVITY FOR DRUGS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(A) in subsection (b), by adding at the end the following:

"(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraph (1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G."; and

(B) in subsection (c), by adding at the end the following:

"(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraph (1) to the lengths of the exclu-

sivity periods after application of pediatric exclusivity, the 6-month extensions described in paragraph (1) shall be in addition to any extensions under section 505G.".

(2) RELATION TO EXCLUSIVITY FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT ARE DRUGS.—Subsection (b) of section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—

(A) by amending the subsection heading to read as follows: "RELATION TO PEDIATRIC EXCLUSIVITY AND EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—"; and

(B) by striking "any extension of the period under section 505A" and inserting "any extension of the periods under sections 505A and 505G, as applicable,".

(3) RELATION TO PEDIATRIC EXCLUSIVITY FOR BIOLOGICAL PRODUCTS.—Section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) is amended by adding at the end the following:

"(5) RELATION TO EXCLUSIVITY FOR A BIOLOGICAL PRODUCT APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Not-

withstanding the references in paragraphs (2)(A), (2)(B), (3)(A), and (3)(B) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in such paragraphs shall be in addition to any extensions under section 505G.".

(d) GAO REPORT.—

(1) IN GENERAL.—Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall issue a report on—

(A) the extent to which this Act, including the amendments made by this Act, provides targeted incentives to develop, and increased availability to, safe and effective treatments for rare diseases and conditions, and recommendations for expanding such availability;

(B) with respect to each drug designated under section 505G(a)(1) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a))—

(i) any change to the cost per unit of such drug following the approval of an application or supplemental application de-

scribed in section 505G(a)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act;

(ii) to the extent practicable, the extent to which rebates and other price concessions reduce the cost of such drug; and

(iii) to the extent practicable, the extent to which such drug contributes to reduced health care costs through prevention or reduced use of hospital and other health care services; and

(C) whether there are barriers to indication-based pricing or value-based pricing for manufacturers of drugs designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) as drugs for a rare disease or condition.

(2) HHS ACTION.—Not later than 1 year after the date on which the Comptroller General issues the report under paragraph (1), the Secretary of Health and Human Services shall implement the recommendations described in paragraph (1)(A) or submit to Congress a report on the reasons why such secretary cannot implement such recommendations.

(e) TECHNICAL CORRECTIONS.—Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), in the matter following paragraph (2), by striking "such drug for such disease or condition" and inserting "the same drug for the same disease or condition";

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "If an application" and all that follows through "such license if" and inserting "During the 7-year period described in subsection (a) for an approved application under section 505 or license under section 351 of the Public Health Service Act, the Secretary may approve an application or issue a license for a drug that is otherwise the same, as determined by the Secretary, as the already approved drug for the same rare disease or condition if";

(B) in paragraph (1), by striking "notice" and all that follows through "assure" and inserting "of exclusive approval or licensure notice and opportunity for the submission of views, that during such period the holder of the

exclusive approval or licensure cannot ensure"; and

(C) in paragraph (2), by striking "such holder provides" and inserting "the holder provides"; and

(3) by adding at the end the following:

"(c) CONDITION OF CLINICAL SUPERIORITY.—

"(1) IN GENERAL.—If a sponsor of a drug that is designated under section 526 and is otherwise the same, as determined by the Secretary, as an already approved or licensed drug is seeking exclusive approval or exclusive licensure described in subsection (a) for the same rare disease or condition as the already approved drug, the Secretary shall require such sponsor, as a condition of such exclusive approval or licensure, to demonstrate that such drug is clinically superior to any already approved or licensed drug that is the same drug.

"(2) DEFINITION.—For purposes of paragraph (1), the term 'clinically superior' with respect to a drug means that the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care.

"(d) REGULATIONS.—The Secretary may promulgate regulations for the implementation of subsection (c). Until such time as the Secretary promulgates regulations in accordance with this subsection, any definitions set forth in regulations implementing this section that were promulgated prior to the date of enactment of the FDA Reauthorization Act of 2017 shall continue to apply.".

BAI17371 S.L.C.

AMENDMENT NO. 1 Calendar No._____

Purpose: To protect the core package of 10 essential health benefits.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on Health, Education, Labor and Pensions and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Murphy, Ms. Baldwin, Ms. Warren

Viz:

At the appropriate place, insert the following:

SEC. ___. PROTECTION OF ESSENTIAL HEALTH BENEFITS.

Notwithstanding any other provision of law, no waiver or exception may be provided to any State with respect to the inclusion in health insurance coverage of the core package of 10 essential health benefits as defined by the Secretary of Health and Human Services under section 1302 of the Patient Protection and Affordable Care Act (42 U.S.C. 18022).

BAI17372 S.L.C.

AMENDMENT NO. 2 Calendar No._____

Purpose: To protect the health insurance coverage of mental health and substance use disorder services.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on Health, Education, Labor and Pensions and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Murphy, Ms. Baldwin, Ms. Warren

Viz:

At the appropriate place, insert the following:

SEC. ___. MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES.

Notwithstanding any other provision of law, no waiver or exception may be provided to any State with respect to the inclusion in health insurance coverage offered in the individual and small group markets of mental health and substance use disorder services as essential health benefits under section 1302 of the Patient Protection and Affordable Care Act (42 U.S.C. 18022).

BAI17391 S.L.C.

AMENDMENT NO. 3 Calendar No._____

Purpose: To ensure that seniors are not charged premiums more than 3 times higher than the premiums charged to younger adult for health insurance coverage.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on Health, Education, Labor and Pensions and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Murphy, Ms. Baldwin, Ms. Warren

Viz:

At the appropriate place, insert the following:

SEC. ___. NO WAIVER FROM AGE-RATING BANDS.

Notwithstanding any other provision of law, there shall be no waivers granted from the 3 to 1 age rating band imposed under section 2701(a)(1)(A)(iii) of the Public Health Service Act (42 U.S.C. 300gg(a)(1)(A)(iii)).

BAI17392 S.L.C.

AMENDMENT NO. 4 Calendar No._____

Purpose: To protect individuals with pre-existing conditions.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on Health, Education, Labor and Pensions and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Murphy, Ms. Baldwin, Ms. Warren

Viz:

At the appropriate place, insert the following:

SEC. ___. PROTECTING INDIVIDUALS WITH PRE-EXISTING CONDITIONS.

Notwithstanding any other provision of law, there shall be no waiver granted from the requirements of sections 2701 and 2705(b) of the Public Health Service Act (42 U.S.C. 300gg and 300gg-4(b)).

TAM17979 S.L.C.

Patty Murray

AMENDMENT NO. 1 Calendar No._____

Purpose: To make a technical correction.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mrs. MURRAY

Viz:

On page 88, line 18, strike "section 312.47(b)" and insert "section 312.82(b)".

TAM17917 S.L.C. Patty Murray

AMENDMENT NO. 2 Calendar No._____

Purpose: To clarify the process for the review of device applications with respect to postmarket activities.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

At the end of section 202, add the following:

(5) by amending subparagraph (J) of paragraph (9) (as redesignated by paragraph (1)) to read as follows:

"(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act and supporting pilot projects under section 519(i).".

TAM17972

Paul Amdt #1

S.L.C.

AMENDMENT NO. 1 Calendar No._____

Purpose: To permit the use of clinical investigational data from outside the United States in certain circumstances.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. PAUL

Viz:

At the appropriate place, insert the following:

SEC. _____. USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.

Section 569B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8b) is amended—

(1) in subsection (a)—

(A) by striking "In determining" and inserting "Subject to subsection (c), in determining";

(B) by inserting "or section 351 of the Public Health Service Act" after "this chapter"; and

(C) by striking ", including the European Union, if the applicant demonstrates that such data are" and inserting "unless the Secretary determines the data is not";

(2) in subsection (b), by striking ", including in the European Union,"; and

(3) by adding at the end the following:

"(c) APPLICATIONS FOR A DRUG THAT HAS BEEN APPROVED OUTSIDE THE US.—

"(1) IN GENERAL.—In the case of an application for approval or clearance of a drug, biological product, or device under this chapter or section 351 of the Public Health Service Act where such drug, biological product, or device has been approved in a country described in paragraph (2), within the timelines established in the letters referred to in section 101(b) of the Prescription Drug User Fee Amendments of 2017 in the case of a drug or within the timelines established in the letters referred to in section 201(b) of the Medical Device User Fee Amendments of 2017 in the case of a device, or such

additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall—

"(A) approve the application, if the Secretary finds no grounds for denying approval of the application; or

"(B) provide written notice to the sponsor of the application of a finding that is grounds for denying approval, including the rationale for such finding, and provide the sponsor an opportunity for a hearing.

"(2) APPLICABLE COUNTRIES.—

"(A) IN GENERAL.—Subject to subparagraph (B), the countries described in this paragraph are—

"(i) Australia;

"(ii) Austria;

"(iii) Belgium;

"(iv) Canada;

"(v) Chile;

"(vi) Czech Republic;

"(vii) Denmark;

"(viii) Estonia;

"(ix) Finland;

"(x) France;

"(xi) Germany;

"(xii) Greece;

"(xiii) Hungary;

"(xiv) Iceland;

"(xv) Ireland;

"(xvi) Israel;

"(xvii) Italy;

"(xviii) Japan;

"(xix) Korea;

"(xx) Latvia;

"(xxi) Luxembourg;

"(xxii) Mexico;

"(xxiii) Netherlands;

"(xxiv) New Zealand;

"(xxv) Norway;

"(xxvi) Poland;

"(xxvii) Portugal;

"(xxviii) Slovak Republic;

"(xxix) Slovenia;

"(xxx) Spain;

"(xxxi) Sweden;

"(xxxii) Switzerland;

"(xxxiii) Turkey; and

"(xxxiv) United Kingdom.

"(B) REVISIONS TO LIST.—The Secretary may add countries to, or remove countries from,

the list under subparagraph (A), as the Secretary determines appropriate.".

TAM17985

Paul Amdt. #2

S.L.C.

AMENDMENT NO. 2 Calendar No._____

Purpose: To establish criteria for issuing regulations for food additives.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

At the appropriate place, add the following:

SEC. _____. FOOD ADDITIVES.

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(a)) is amended—

(1) in paragraph (2), by striking "; or" and inserting ";";

(2) in paragraph (3)(B), by striking the period and inserting "; or"; and

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

"(4) there is in effect a regulation, approval, or other determination issued by one or more developed countries, including a country in the European Union, prescribing the conditions under which such additive may be safely used, and the additive and its use or intended use are in conformity with such regulation, approval, or other determination, unless the Secretary by regulation determines—

"(A) the additive is unsafe in its intended use under the conditions prescribed in such regulation, approval, or other determination; or

"(B) the regulation, approval, or other determination process in a particular country is not capable of prescribing the conditions under which an additive may be safely used.".

TAM17967

Bernie Sanders

S.L.C.

Amendment #2

AMENDMENT NO._____ Calendar No._____

Purpose: To allow for the importation from Canada of safe and affordable drugs by wholesale distributors, pharmacies, and individuals.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. SANDERS

Viz:

At the end of title XVIII, add the following:

SEC. 807. IMPORTING AFFORDABLE AND SAFE DRUGS FROM CANADA.

(a) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended to read as follows:

"SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE DRUGS BY WHOLESALE DISTRIBUTORS, PHARMACIES, AND INDIVIDUALS.

"(a) IN GENERAL.—Not later than 180 days after the date of enactment of the FDA Reauthorization Act of 2017, the Secretary shall promulgate regulations permitting the importation of qualifying prescription drugs into the United States, in accordance with this section.

"(b) DEFINITIONS.—For purposes of this section:

"(1) CERTIFIED FOREIGN SELLER.—The term 'certified foreign seller' means a licensed foreign pharmacy or foreign wholesale distributor that the Secretary certifies under subsection (d)(1)(B), that pays the fee required under subsection (d)(1)(C), and that is included on the list described in subsection (c).

"(2) FOREIGN WHOLESALE DISTRIBUTOR.—The term 'foreign wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager) engaged in wholesale distribution.

"(3) IMPORTER.—The term 'importer' means a dispenser (as defined in section 581(3)) or wholesale distributor registered under section 503(e) who im-

ports prescription drugs into the United States in accordance with this section.

"(4) LICENSED FOREIGN PHARMACY.—The term 'licensed foreign pharmacy' means a pharmacy located in Canada that—

"(A) operates in accordance with applicable pharmacy standards set forth by the provincial pharmacy rules and regulations enacted in Canada; and

"(B) is licensed to operate and dispense prescription drugs to individuals in Canada.

"(5) QUALIFYING PRESCRIPTION DRUG.—The term 'qualifying prescription drug'—

"(A) means a prescription drug that—

"(i) is approved for use in patients, and marketed, in Canada;

"(ii) is manufactured in a facility registered under subsection (b)(1) or (i) of section 510 that is in compliance with good manufacturing practices regulations of the Food and Drug Administration;

"(iii) has the same active ingredient or ingredients, route of administration, and strength as a prescription drug approved under chapter V, or, for purposes of sub-

paragraph (B)(iv), is biosimilar to an approved biological product and has the same route of administration and strength as the approved biological product; and

"(iv) is labeled in accordance with—

"(I) the laws of Canada; and

"(II) the requirements promulgated by the Secretary, which shall include labeling in English;

"(B) with respect to importers only, includes—

"(i) peritoneal dialysis solution;

"(ii) insulin;

"(iii) a drug for which a risk evaluation and mitigation strategy is required under section 505–1;

"(iv) biological products, as defined in section 351 of the Public Health Service Act that are proteins (except any chemically synthesized polypeptides) or analogous products; and

"(v) intravenously infused drugs; and

"(C) does not include—

"(i) a controlled substance (as defined in section 102 of the Controlled Substances Act);

"(ii) an anesthetic drug inhaled during surgery; or

"(iii) a compounded drug.

"(6) VALID PRESCRIPTION.—The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

"(A) a practitioner who has conducted at least one in-person medical evaluation of the patient; or

"(B) a covering practitioner.

"(c) PUBLICATION OF CERTIFIED FOREIGN SELLERS.—The Secretary shall publish on a dedicated Internet Web site a list of certified foreign sellers, including the Internet Web site address, physical address, and telephone number of each such certified foreign seller.

"(d) ADDITIONAL CRITERIA.—

"(1) CERTIFIED FOREIGN SELLERS.—

"(A) IN GENERAL.—To be a certified foreign seller, such seller shall—

"(i) be certified by the Secretary in accordance with subparagraph (B);

"(ii) pay the registration fee established under subparagraph (C); and

"(iii) sell only qualifying prescription drugs to importers or individuals who import prescription drugs into the United States in accordance with this section.

"(B) CERTIFICATION.—To be a certified foreign seller, the Secretary shall certify that such seller—

"(i) is a foreign wholesale distributor or licensed foreign pharmacy operating an establishment, which may include an online foreign pharmacy, that is located in Canada;

"(ii) is engaged in the distribution or dispensing of a prescription drug that is imported or offered for importation into the United States;

"(iii) has been in existence for a period of at least 5 years preceding the date of such certification and has a purpose other than to participate in the program established under this section;

"(iv) in the case of a certified foreign seller that is a licensed foreign pharmacy,

agrees to dispense a qualifying prescription drug to an individual in the United States only after receiving a valid prescription, as described in paragraph (2)(C);

"(v) has processes established by the seller, or participates in another established process, to certify that the physical premises and data reporting procedures and licenses are in compliance with all applicable laws and regulations of Canada and has implemented policies designed to monitor ongoing compliance with such laws and regulations;

"(vi) conducts or commits to participate in ongoing and comprehensive quality assurance programs and implements such quality assurance measures, including blind testing, to ensure the veracity and reliability of the findings of the quality assurance program;

"(vii) agrees that, pursuant to subsection (f), laboratories approved by the Secretary may be authorized to conduct product testing to determine the chemical

authenticity of sample pharmaceutical products;

"(viii) agrees to notify the Secretary, importers, and individuals of product recalls in Canada and agrees to cease, or refrain from, exporting such product;

"(ix) has established, or will establish or participate in, a process for resolving grievances, as defined by the Secretary, and will be held accountable for violations of established guidelines and rules;

"(x) except as otherwise permitted under this section, does not sell products that the seller could not otherwise legally sell in Canada to customers in the United States; and

"(xi) meets any other criteria established by the Secretary.

"(C) CERTIFICATION FEE.—Not later than 30 days before the start of each fiscal year, the Secretary shall establish a fee to be collected from foreign sellers for such fiscal year that are certified under subparagraph (B), in an amount that is sufficient, and not more than necessary, to pay the costs of administering the program

under this section, and enforcing this section pursuant to section 303(h), for that fiscal year.

"(D) RECERTIFICATION.—A certification under subparagraph (B) shall be in effect for a period of 2 years, or until there is a material change in the circumstances under which the foreign seller meets the requirements under such subparagraph, whichever occurs earlier. A foreign seller may reapply for certification under such subparagraph (B), in accordance with a process established by the Secretary.

"(2) INDIVIDUALS.—An individual may import a qualifying prescription drug described in subsection (b) from Canada if such drug—

"(A) is dispensed, including through an online pharmacy, by a certified foreign seller that is a licensed foreign pharmacy;

"(B) is purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply; and

"(C) is filled only after providing to the licensed foreign pharmacy a valid prescription issued by a health care practitioner licensed to practice in a State in the United States.

"(e) LABELING.—Any qualifying prescription drug imported that meets the labeling requirements described in subsection (b)(5)(A)(iv) is deemed not misbranded for purposes of section 502.

"(f) DRUG TESTING LABORATORIES.—The Secretary may approve one or more laboratories to conduct random testing of prescription drugs sold by certified foreign sellers to assess the chemical authenticity of such drugs.

"(g) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement)—

"(1) to discriminate by charging a higher price for a prescription drug sold to a certified foreign seller that sells such drug to an importer in accordance with this section than the price that is charged, inclusive of rebates or other incentives to the country from which the drug is exported, to another person that is in the same country and that does not import such a drug into the United States in accordance with this section;

"(2) except with respect to a prescription drug on the drug shortage list under section 506E, discriminate by denying, restricting, or delaying supplies of a prescription drug to a certified foreign sell-

er, on account of such seller's status as a certified foreign seller, that sells such drug to an importer in accordance with this section, or by publicly, privately, or otherwise refusing to do business with such a certified foreign seller on account of such seller's status as a certified foreign seller;

"(3) cause there to be a difference (including a difference in active ingredient, route of administration, bioequivalence, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in Canada, for the purpose of avoiding sales by certified foreign sellers; or

"(4) except with respect to a prescription drug on the drug shortage list under section 506E, engage in any other action to restrict, prohibit, or delay the importation of a prescription drug under this section.

"(h) INFORMATION AND RECORDS.—

"(1) BIANNUAL REPORTS.—Each importer shall submit biannual reports to the Secretary which shall contain, for each qualifying prescription drug imported into the United States—

"(A) the unique facility identifier of the manufacturer of the drug, described in section 510;

"(B) the transaction information described in section 581(26) (other than the information described in subparagraph (C)); and

"(C) the price paid by the importer for the drug.

"(2) MAINTENANCE OF RECORDS BY SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be appropriate.

"(i) SUSPENSION OF IMPORTATION.—

"(1) PATTERNS OF NONCOMPLIANCE.—The Secretary shall require that importation of a specific qualifying prescription drug or importation by a specific certified foreign seller or importer pursuant to this section be immediately suspended if the Secretary determines that there is a pattern of importation of such specific drug or by such specific seller or importer that involves counterfeit drugs, drugs that have been recalled or withdrawn, or drugs in violation of any requirement of this section, until an investigation is completed and the Secretary deter-

mines that importation of such drug or by such seller or importer does not endanger the public health.

"(2) TEMPORARY SUSPENSION.—The Secretary may require that importation of a specific qualifying prescription drug or importation by a specific certified foreign seller or importer pursuant to this section be temporarily suspended if, with respect to such drug, seller, or importer, there is a violation of any requirement of this section or if the Secretary determines that importation of such drug or by such seller or importer might endanger the public health. Such temporary suspension shall apply until the Secretary completes an investigation and determines that importation of such drug or by such seller or importer does not endanger the public health.

"(j) SUPPLY CHAIN SECURITY.—

"(1) PURCHASE FROM REGISTERED FACILITIES AND CERTIFIED FOREIGN SELLERS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs only from manufacturers or entities registered under section 510 or other certified foreign sellers.

"(B) EXCEPTION.—Certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs from foreign sellers in Canada or another permitted country, even if such foreign seller is not a manufacturer registered under section 510 or a certified foreign seller, if the Secretary enters into a memorandum of understanding or cooperative agreement with Canada, or such other permitted country, to ensure compliance, to the extent appropriate and feasible, with subchapter H of chapter V. The Secretary shall seek to enter into such a memorandum of understanding or cooperative agreement with Canada.

"(2) IMPORTATION TRACING.—Certified foreign sellers shall provide importers with the unique facility identifier associated with the manufacturer registered under section 510 of the qualifying prescription drug and the information under paragraph (25), paragraph (26) (other than subparagraph (C)), and subparagraphs (D), (F), and (G) of paragraph (27) of section 581. Certified foreign sellers shall provide such information to individuals purchasing such drugs, upon request.

"(k) REMS.—In the case of an importer that imports a qualifying prescription drug, where the drug with the same active ingredient or ingredients (or that is biosimilar to an approved biological product), route of administration, and strength that is approved under chapter V or section 351 of the Public Health Service Act is subject to elements to assure safe use under section 505–1, such importer shall be subject to such elements to assure safe use, as applicable and appropriate.

"(l) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.".

(b) PENALTIES WITH RESPECT TO ONLINE PHARMACIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

"(h) In the case of person operating an Internet website, whether in the United States or in another country, that violates section 301(aa) by—

"(1) selling, by means of the Internet, with the intent to defraud or mislead or with reckless disregard for safety of the public, an adulterated or counterfeit drug to an individual in the United States; or

"(2) dispenses, by means of the Internet, a drug to an individual in the United States who the person knows or has reasonable cause to believe, does not possess a valid prescription for that drug, such person shall be imprisoned for not more than 10 years or fined not more than $250,000.".

(c) NO PREEMPTION.—Nothing in this section, including the amendments made by this section, shall be construed to preempt, alter, displace, abridge, or supplant any remedy available under any State or Federal law, including common law, that provides a remedy for civil relief.

(d) REPORTS.—

(1) HHS.—Not later than 1 year after the date on which final regulations are promulgated to carry out section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as amended by this section, and every 2 years thereafter, the Secretary of Health and Human Services, after consultation with appropriate Federal agencies, shall submit to Congress and make public a report on the importation of drugs into the United States.

(2) GAO REPORT.—Not later than 18 months after the date on which final regulations are promulgated to carry out section 804 of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 384), as amended by this section, the Comptroller General of the United States shall submit to Congress a report containing an analysis of the implementation of the amendments made by this section, including a review of drug safety and cost-savings and expenses, including cost-savings to consumers in the United States and trans-shipment and importation tracing processes, resulting from such implementation.

Bernie Sanders

TAM17935 S.L.C.

Amendment #1

AMENDMENT NO._____ Calendar No._____

Purpose: To allow for the importation of safe and affordable drugs by wholesale distributors, pharmacies, and individuals.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. SANDERS

Viz:

At the end of title XVIII, add the following:

SEC. 807. IMPORTING AFFORDABLE AND SAFE DRUGS.

(a) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended to read as follows:

"SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE DRUGS BY WHOLESALE DISTRIBUTORS, PHARMACIES, AND INDIVIDUALS.

"(a) IN GENERAL.—Not later than 180 days after the date of enactment of the FDA Reauthorization Act

of 2017, the Secretary shall promulgate regulations permitting the importation of qualifying prescription drugs into the United States, in accordance with this section.

"(b) DEFINITIONS.—For purposes of this section:

"(1) CERTIFIED FOREIGN SELLER.—The term 'certified foreign seller' means a licensed foreign pharmacy or foreign wholesale distributor that the Secretary certifies under subsection (d)(1)(B), that pays the fee required under subsection (d)(1)(C), and that is included on the list described in subsection (e).

"(2) FOREIGN WHOLESALE DISTRIBUTOR.—The term 'foreign wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager) engaged in wholesale distribution.

"(3) IMPORTER.—The term 'importer' means a dispenser (as defined in section 581(3)) or wholesale distributor registered under section 503(e) who imports prescription drugs into the United States in accordance with this section.

"(4) LICENSED FOREIGN PHARMACY.—The term 'licensed foreign pharmacy' means a pharmacy

located in Canada, or subject to subsection (e), another applicable country, that—

"(A) operates in accordance with applicable pharmacy standards set forth by the provincial pharmacy rules and regulations enacted in Canada, or, subject to subsection (e), such applicable rules and regulations of the permitted country in which such seller is located; and

"(B) is licensed to operate and dispense prescription drugs to individuals in Canada, or, subject to subsection (e), the permitted country in which the pharmacy is located.

"(5) QUALIFYING PRESCRIPTION DRUG.—The term 'qualifying prescription drug'—

"(A) means a prescription drug that—

"(i) is approved for use in patients, and marketed, in Canada, or subject to subsection (e), approved for use in patients, and marketed, in another permitted country;

"(ii) is manufactured in a facility registered under subsection (b)(1) or (i) of section 510 that is in compliance with good manufacturing practices regulations of the Food and Drug Administration;

"(iii) has the same active ingredient or ingredients, route of administration, and strength as a prescription drug approved under chapter V, or, for purposes of subparagraph (B)(iv), is biosimilar to an approved biological product and has the same route of administration and strength as the approved biological product; and

"(iv) is labeled in accordance with—

"(I) the laws of Canada, or another country from which importation is permitted pursuant to subsection (e); and

"(II) the requirements promulgated by the Secretary, which shall include labeling in English;

"(B) with respect to importers only, includes—

"(i) peritoneal dialysis solution;

"(ii) insulin;

"(iii) a drug for which a risk evaluation and mitigation strategy is required under section 505–1;

"(iv) biological products, as defined in section 351 of the Public Health Service

Act that are proteins (except any chemically synthesized polypeptides) or analogous products; and

"(v) intravenously infused drugs; and

"(C) does not include—

"(i) a controlled substance (as defined in section 102 of the Controlled Substances Act);

"(ii) an anesthetic drug inhaled during surgery; or

"(iii) a compounded drug.

"(6) VALID PRESCRIPTION.—The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

"(A) a practitioner who has conducted at least one in-person medical evaluation of the patient; or

"(B) a covering practitioner.

"(c) PUBLICATION OF CERTIFIED FOREIGN SELLERS.—The Secretary shall publish on a dedicated Internet Web site a list of certified foreign sellers, including the Internet Web site address, physical address, and telephone number of each such certified foreign seller.

"(d) ADDITIONAL CRITERIA.—

"(1) CERTIFIED FOREIGN SELLERS.—

"(A) IN GENERAL.—To be a certified foreign seller, such seller shall—

"(i) be certified by the Secretary in accordance with subparagraph (B);

"(ii) pay the registration fee established under subparagraph (C); and

"(iii) sell only qualifying prescription drugs to importers or individuals who import prescription drugs into the United States in accordance with this section.

"(B) CERTIFICATION.—To be a certified foreign seller, the Secretary shall certify that such seller—

"(i) is a foreign wholesale distributor or licensed foreign pharmacy operating an establishment, which may include an online foreign pharmacy, that is located in Canada, or, subject to subsection (e), another permitted country;

"(ii) is engaged in the distribution or dispensing of a prescription drug that is imported or offered for importation into the United States;

"(iii) has been in existence for a period of at least 5 years preceding the date of such certification and has a purpose other than to participate in the program established under this section;

"(iv) in the case of a certified foreign seller that is a licensed foreign pharmacy, agrees to dispense a qualifying prescription drug to an individual in the United States only after receiving a valid prescription, as described in paragraph (2)(C);

"(v) has processes established by the seller, or participates in another established process, to certify that the physical premises and data reporting procedures and licenses are in compliance with all applicable laws and regulations of Canada, or, subject to subsection (e), the permitted country in which the seller is located, and has implemented policies designed to monitor ongoing compliance with such laws and regulations;

"(vi) conducts or commits to participate in ongoing and comprehensive quality assurance programs and implements such

quality assurance measures, including blind testing, to ensure the veracity and reliability of the findings of the quality assurance program;

"(vii) agrees that, pursuant to subsection (g), laboratories approved by the Secretary may be authorized to conduct product testing to determine the chemical authenticity of sample pharmaceutical products;

"(viii) agrees to notify the Secretary, importers, and individuals of product recalls in Canada, or pursuant to subsection (e), the permitted country in which the seller is located, and agrees to cease, or refrain from, exporting such product;

"(ix) has established, or will establish or participate in, a process for resolving grievances, as defined by the Secretary, and will be held accountable for violations of established guidelines and rules;

"(x) except as otherwise permitted under this section, does not sell products that the seller could not otherwise legally sell in Canada, or, subject to subsection

(e), the permitted country in which such seller is located to customers in the United States; and

"(xi) meets any other criteria established by the Secretary.

"(C) CERTIFICATION FEE.—Not later than 30 days before the start of each fiscal year, the Secretary shall establish a fee to be collected from foreign sellers for such fiscal year that are certified under subparagraph (B), in an amount that is sufficient, and not more than necessary, to pay the costs of administering the program under this section, and enforcing this section pursuant to section 303(h), for that fiscal year.

"(D) RECERTIFICATION.—A certification under subparagraph (B) shall be in effect for a period of 2 years, or until there is a material change in the circumstances under which the foreign seller meets the requirements under such subparagraph, whichever occurs earlier. A foreign seller may reapply for certification under such subparagraph (B), in accordance with a process established by the Secretary.

"(2) INDIVIDUALS.—An individual may import a qualifying prescription drug described in sub-

section (b) from Canada or another country pursuant to subsection (e) if such drug—

"(A) is dispensed, including through an online pharmacy, by a certified foreign seller that is a licensed foreign pharmacy;

"(B) is purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply; and

"(C) is filled only after providing to the licensed foreign pharmacy a valid prescription issued by a health care practitioner licensed to practice in a State in the United States.

"(e) IMPORTATION FROM OTHER COUNTRIES.—Beginning on the date that is 2 years after the date on which final regulations are promulgated to carry out this section, if, based on a review of the evidence obtained after such effective date, including the reports submitted under section 807(d) of the FDA Reauthorization Act of 2017, that importation of qualifying prescription drugs from Canada under this section resulted in cost savings for consumers in the United States and increased access to safe medication, the Secretary shall have the authority to permit importation of qualifying prescription drugs by importers and individuals from, in addition to Canada, any country that—

"(1) is a member of the Organisation for Economic Co-operation and Development; and

"(2) has statutory or regulatory standards for the approval and sale of prescription drugs that are comparable to the standards in the United States and that—

"(A) authorizes the approval of drugs only if a drug has been determined to be safe and effective by experts employed by or acting on behalf of a governmental entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

"(B) requires that any determination of safety and effectiveness described in subparagraph (A) be made on the basis of adequate and well-controlled investigations, including clinical investigations, as appropriate, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

"(C) requires the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of drugs in the country to be adequate to preserve the identity, quality, purity, and strength of the drugs; and

"(D) requires the reporting of adverse reactions to drugs and establish procedures to recall, and withdraw approval of, drugs found not to be safe or effective.

"(f) LABELING.—Any qualifying prescription drug imported that meets the labeling requirements described in subsection (b)(5)(A)(iv) is deemed not misbranded for purposes of section 502.

"(g) DRUG TESTING LABORATORIES.—The Secretary may approve one or more laboratories to conduct random testing of prescription drugs sold by certified foreign sellers to assess the chemical authenticity of such drugs.

"(h) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement)—

"(1) to discriminate by charging a higher price for a prescription drug sold to a certified foreign seller that sells such drug to an importer in accordance with this section than the price that is charged, inclusive of rebates or other incentives to the country from which the drug is exported, to another person that is in the same country and that does not

import such a drug into the United States in accordance with this section;

"(2) except with respect to a prescription drug on the drug shortage list under section 506E, discriminate by denying, restricting, or delaying supplies of a prescription drug to a certified foreign seller, on account of such seller's status as a certified foreign seller, that sells such drug to an importer in accordance with this section, or by publicly, privately, or otherwise refusing to do business with such a certified foreign seller on account of such seller's status as a certified foreign seller;

"(3) cause there to be a difference (including a difference in active ingredient, route of administration, bioequivalence, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in Canada or another permitted country, subject to subsection (e), for the purpose of avoiding sales by certified foreign sellers; or

"(4) except with respect to a prescription drug on the drug shortage list under section 506E, engage in any other action to restrict, prohibit, or

delay the importation of a prescription drug under this section.

"(i) INFORMATION AND RECORDS.—

"(1) BIANNUAL REPORTS.—Each importer shall submit biannual reports to the Secretary which shall contain, for each qualifying prescription drug imported into the United States—

"(A) the unique facility identifier of the manufacturer of the drug, described in section 510;

"(B) the transaction information described in section 581(26) (other than the information described in subparagraph (C)); and

"(C) the price paid by the importer for the drug.

"(2) MAINTENANCE OF RECORDS BY SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be appropriate.

"(j) SUSPENSION OF IMPORTATION.—

"(1) PATTERNS OF NONCOMPLIANCE.—The Secretary shall require that importation of a specific qualifying prescription drug or importation by a specific certified foreign seller or importer pursuant to

this section be immediately suspended if the Secretary determines that there is a pattern of importation of such specific drug or by such specific seller or importer that involves counterfeit drugs, drugs that have been recalled or withdrawn, or drugs in violation of any requirement of this section, until an investigation is completed and the Secretary determines that importation of such drug or by such seller or importer does not endanger the public health.

"(2) TEMPORARY SUSPENSION.—The Secretary may require that importation of a specific qualifying prescription drug or importation by a specific certified foreign seller or importer pursuant to this section be temporarily suspended if, with respect to such drug, seller, or importer, there is a violation of any requirement of this section or if the Secretary determines that importation of such drug or by such seller or importer might endanger the public health. Such temporary suspension shall apply until the Secretary completes an investigation and determines that importation of such drug or by such seller or importer does not endanger the public health.

"(k) SUPPLY CHAIN SECURITY.—

"(1) PURCHASE FROM REGISTERED FACILITIES AND CERTIFIED FOREIGN SELLERS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs only from manufacturers or entities registered under section 510 or other certified foreign sellers.

"(B) EXCEPTION.—Certified foreign sellers who sell qualifying prescription drugs for importation into the United States pursuant to this section may purchase such drugs from foreign sellers in Canada or another permitted country, even if such foreign seller is not a manufacturer registered under section 510 or a certified foreign seller, if the Secretary enters into a memorandum of understanding or cooperative agreement with Canada, or such other permitted country, to ensure compliance, to the extent appropriate and feasible, with subchapter H of chapter V. The Secretary shall seek to enter into such a memorandum of understanding or cooperative agreement with Canada and each country from which importation is permitted under subsection (e).

"(2) IMPORTATION TRACING.—Certified foreign sellers shall provide importers with the unique facility identifier associated with the manufacturer registered under section 510 of the qualifying prescription drug and the information under paragraph (25), paragraph (26) (other than subparagraph (C)), and subparagraphs (D), (F), and (G) of paragraph (27) of section 581. Certified foreign sellers shall provide such information to individuals purchasing such drugs, upon request.

"(l) REMS.—In the case of an importer that imports a qualifying prescription drug, where the drug with the same active ingredient or ingredients (or that is biosimilar to an approved biological product), route of administration, and strength that is approved under chapter V or section 351 of the Public Health Service Act is subject to elements to assure safe use under section 505–1, such importer shall be subject to such elements to assure safe use, as applicable and appropriate.

"(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.".

(b) PENALTIES WITH RESPECT TO ONLINE PHARMACIES.—Section 303 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

"(h) In the case of person operating an Internet website, whether in the United States or in another country, that violates section 301(aa) by—

"(1) selling, by means of the Internet, with the intent to defraud or mislead or with reckless disregard for safety of the public, an adulterated or counterfeit drug to an individual in the United States; or

"(2) dispenses, by means of the Internet, a drug to an individual in the United States who the person knows or has reasonable cause to believe, does not possess a valid prescription for that drug, such person shall be imprisoned for not more than 10 years or fined not more than $250,000.".

(c) NO PREEMPTION.—Nothing in this section, including the amendments made by this section, shall be construed to preempt, alter, displace, abridge, or supplant any remedy available under any State or Federal law, including common law, that provides a remedy for civil relief.

(d) REPORTS.—

(1) HHS.—Not later than 1 year after the date on which final regulations are promulgated to carry

out section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as amended by this section, and every 2 years thereafter, the Secretary of Health and Human Services, after consultation with appropriate Federal agencies, shall submit to Congress and make public a report on the importation of drugs into the United States.

(2) GAO REPORT.—Not later than 18 months after the date on which final regulations are promulgated to carry out section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384), as amended by this section, the Comptroller General of the United States shall submit to Congress a report containing an analysis of the implementation of the amendments made by this section, including a review of drug safety and cost-savings and expenses, including cost-savings to consumers in the United States and trans-shipment and importation tracing processes, resulting from such implementation.