

S.L.C.
Lawrence 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:

1 At the end of title VI, insert the following:

2 **SEC. 6 . IMPORTATION REQUIREMENT.**

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

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

- 1 (2) not increase the public's exposure to coun-
- 2 terfeit drugs; and
- 3 (3) not further exacerbate the nationwide opioid
- 4 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:

- 1 At the end of title V, add the following:
- 2 **SEC. 505. DRUG DEVELOPMENT FOR PEDIATRIC CANCER.**
- 3 (a) MOLECULAR TARGETS REGARDING CANCER
- 4 DRUGS.—Section 505B of the Federal Food, Drug, and
- 5 Cosmetic Act (21 U.S.C. 355e) is amended—
- 6 (1) in subsection (a)(2)(A)(i) by striking “prod-
- 7 uct for the claimed indications in all relevant pedi-
- 8 atric subpopulations; and” and inserting “product in
- 9 all relevant pediatric subpopulations—

1 “(I) for the claimed indications;
2 or”.

3 “(II) for a pediatric cancer indi-
4 cation, if the drug is intended for the
5 treatment of an adult cancer and is
6 directed at a molecular target consid-
7 ered to be germane to the growth and
8 progression of such pediatric cancer;
9 and”;

10 (2) in subsection (b)(1)—

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

13 “(A)(i) the drug or biological product is
14 used for a substantial number of pediatric pa-
15 tients—

16 “(I) for the labeled indications; or

17 “(II) for a pediatric cancer indication,
18 if the drug is intended for the treatment of
19 an adult cancer and is directed at a molec-
20 ular target considered to be germane to
21 the growth and progression of such pedi-
22 atric cancer; and”;

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

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

5 “(i) for 1 or more of the claimed indi-
6 cations; or

7 “(ii) for a pediatric cancer indication,
8 if the drug is intended for the treatment of
9 an adult cancer and is directed at a molec-
10 ular target considered to be germane to
11 the growth and progression of such pedi-
12 atric cancer; or”); and

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

15 “(2) the drug or biological product is in a class
16 of products, is for an indication, or is directed at a
17 specific molecular target in an adult cancer and such
18 molecular target is germane to the growth or pro-
19 gression of cancer in a pediatric cancer, for which
20 there is need for additional options.”.

21 (b) EARLY MEETING ON PEDIATRIC STUDY PLAN.—

22 (1) IN GENERAL.—Clause (i) of section
23 505B(e)(2)(C) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 355c(e)(2)(C)) is amended to
25 read as follows:

4

1 “(i) shall meet with the applicant—

2 “(I) if requested by the applicant
3 with respect to a drug that is in-
4 tended to treat a serious or life-
5 threatening disease or condition, to
6 discuss preparation of the initial pedi-
7 atric study plan, not later than the
8 end-of-Phase 1 meeting (as such term
9 is used in section 312.47(b) of title
10 21, Code of Federal Regulations, or
11 successor regulations) or within 30
12 days of receipt of such request, which-
13 ever is later;

14 “(II) to discuss the initial pedi-
15 atric study plan as soon as prac-
16 ticable, but not later than 90 calendar
17 days after the receipt of such plan
18 under subparagraph (A); and

19 “(III) to discuss any scientific or
20 operational challenges that may be the
21 basis of a deferral under subsection
22 (a)(3) or a full or partial waiver under
23 subsection (a)(4);”.

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

4 (A) in the heading of paragraph (2), by
5 striking “MEETING” and inserting “MEETINGS”;

6 (B) in the heading of paragraph (2)(C), by
7 striking “MEETING” and inserting “MEET-
8 INGS”;

9 (C) in clauses (ii) and (iii) of paragraph
10 (2)(C), by striking “no meeting” each place it
11 appears and inserting “no meeting under clause
12 (i)(II)”; and

13 (D) in paragraph (3) by striking “meeting
14 under paragraph (2)(C)(i)” and inserting
15 “meeting under paragraph (2)(C)(i)(II)”.

16 (c) ORPHAN DRUGS.—Section 505B(k) of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355c(k))
18 is amended by inserting “except in the case of a drug or
19 biological product that is intended for the treatment of
20 an adult cancer and is directed at a molecular target con-
21 sidered to be germane to the growth and progression of
22 a pediatric cancer,” after “regulation,”.

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

1 Food and Drugs, shall issue guidance on the implementa-
2 tion of the amendments to section 505B of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 355e) made by
4 this section, including—

5 (1) study designs;

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

11 (3) considerations for implementation of such
12 section 505B, as so amended, and waivers of the re-
13 quirements of such section 505B with regard to mo-
14 lecular targets for which several drugs may be under
15 investigation.

16 (c) APPLICABILITY.—This section and the amend-
17 ments made by this section apply with respect to applica-
18 tions for a drug submitted under section 505 of the Fed-
19 eral Food, Drug, or Cosmetic Act (21 U.S.C. 355) or sec-
20 tion 351 of the Public Health Service Act (42 U.S.C. 262)
21 on or after the date that is 18 months after the date of
22 enactment of this Act.

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

1 (1) in paragraph (10), by striking “; and” and
2 inserting “;”; and

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

5 “(11) an assessment of the impact of the
6 amendments to such section 505B made by the
7 FDA Authorization Act of 2017 on pediatric label-
8 ing of drugs and pediatric labeling of molecularly
9 targeted drugs for the treatment of cancer;

10 “(12) an assessment of the efforts of the Sec-
11 retary to implement the plan developed under sec-
12 tion 505C–1 of the Federal Food, Drug, and Cos-
13 metic Act, regarding earlier submission of pediatric
14 studies under sections 505A and 505B, including—

15 “(A) the average length of time after the
16 approval of an application under section
17 505(b)(1) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 355(b)(1)) before studies
19 conducted pursuant to such sections 505A or
20 505B are completed, submitted, and incor-
21 porated into labeling;

22 “(B) the average length of time after the
23 receipt of a proposed pediatric study request be-
24 fore the Secretary responds to such request;

1 “(C) the average length of time after the
2 submission of a proposed pediatric study re-
3 quest before the Secretary issues a written re-
4 quest for such studies;

5 “(D) the number of written requests issued
6 for each investigational new drug prior to the
7 submission of an application under section
8 505(b)(1) of the Federal Food, Drug, and Cos-
9 metic Act; and

10 “(E) the average number, and range of
11 numbers, of amendments to written requests
12 issued;

13 “(13) a list of sponsors of applications or hold-
14 ers of approved applications who received exclusivity
15 under such section 505A after receiving a letter
16 issued under such section 505B(d)(1) and before the
17 studies referred to in such letter were completed and
18 submitted; and

19 “(14) a list of assessments required under sub-
20 section (a)(2)(A)(i)(II), and (b)(1)(B)(ii) of section
21 505B.”.

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

1 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355a).

3 **SEC. 506. IMPROVING THE TIMELINESS OF PEDIATRIC**
4 **STUDIES.**

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

9 “(7) **INFORMING INTERNAL REVIEW COM-**
10 **MITTEE.**—The Secretary shall provide to the com-
11 mittee referred to in paragraph (1) any response
12 issued to an applicant or holder with respect to a
13 proposed pediatric study request.”.

14 (b) **ACTION ON SUBMISSIONS.**—Section 505A(d) of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 355a(d)) is amended—

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

19 (2) by inserting after paragraph (2) the fol-
20 lowing:

21 “(3) **ACTION ON SUBMISSIONS.**—The Secretary
22 shall review and act upon a submission of a pro-
23 posed pediatric study request or a sponsor’s pro-
24 posed amendment to a written request for pediatric
25 studies within 120 days of the submission.”.

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

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

16 (2) earlier issuance of written requests for a pe-
17 diatric study under such section 505A, including for
18 investigational new drugs prior to the submission of
19 an application under section 505(b)(1) of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.
21 355(b)(1)); and

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

1 **SEC. 507. NEONATOLOGY EXPERTISE.**

2 Section 6(d) of the Best Pharmaceuticals for Chil-
3 dren Act (21 U.S.C. 393a(d)) is amended by striking “For
4 the 5-year period beginning on the date of enactment of
5 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:

- 1 At the end of title V, insert the following:
- 2 **SEC. 505. DEVELOPMENT OF DRUGS AND BIOLOGICAL**
- 3 **PRODUCTS FOR PEDIATRIC CANCERS.**
- 4 (a) MOLECULAR TARGETS REGARDING CANCER
- 5 DRUGS.—Section 505B of the Federal Food, Drug, and
- 6 Cosmetic Act (21 U.S.C. 355c) is amended—
- 7 (1) in subsection (a)—
- 8 (A) in paragraph (2)(A)(i) by striking
- 9 “product for the claimed indications in all rel-
- 10 evant pediatric subpopulations; and” and in-

1 serting “product in all relevant pediatric sub-
2 populations—

3 “(I) for the claimed indications;
4 or”.

5 “(II) for one pediatric cancer in-
6 dication, if the drug or biological
7 product is—

8 “(aa) the subject of an origi-
9 nal application that is submitted
10 not less than 2 years after the
11 date of enactment of the FDA
12 Reauthorization Act of 2017;

13 “(bb) intended for the treat-
14 ment of an adult cancer;

15 “(cc) determined by sci-
16 entific evidence to be directed at
17 a molecular target, on the basis
18 of data the Secretary determines
19 to be adequate, to be germane to
20 the development or growth of
21 such pediatric cancer; and

22 “(dd) on the list under sub-
23 section (m) at the time of sub-
24 mission of such original applica-
25 tion; and”;

1 (B) by adding at the end the following:

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

7 (2) in subsection (b)—

8 (A) in paragraph (1)—

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

11 “(A)(i) the drug or biological product is
12 used for a substantial number of pediatric pa-
13 tients—

14 “(I) for the labeled indications; or

15 “(II) for one pediatric cancer indica-
16 tion, if the drug or biological product is—

17 “(aa) the subject of an original
18 application that is submitted not less
19 than 2 years after the date of enact-
20 ment of the FDA Reauthorization Act
21 of 2017;

22 “(bb) intended for the treatment
23 of an adult cancer; and

24 “(cc) determined by scientific evi-
25 dence to be directed at a molecular

1 target, on the basis of data the Sec-
2 retary determines to be adequate, to
3 be germane to the development or
4 growth of such pediatric cancer; and

5 “(dd) on the list under sub-
6 section (m) at the time of submission
7 of such original application; and”;
8 (ii) by amending subparagraph (B) to
9 read as follows:

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

14 “(i) for 1 or more of the claimed indi-
15 cations; or

16 “(ii) for one pediatric cancer indica-
17 tion, if the drug or biological product is—

18 “(I) the subject of an original ap-
19 plication that is submitted not less
20 than 2 years after the date of enact-
21 ment of the FDA Reauthorization Act
22 of 2017;

23 “(II) intended for the treatment
24 of an adult cancer;

1 “(III) determined by scientific
2 evidence to be directed at a molecular
3 target, on the basis of data the Sec-
4 retary determines to be adequate, to
5 be germane to the development or
6 growth of such pediatric cancer; and

7 “(IV) on the list under sub-
8 section (m) at the time of submission
9 of such original application; or”; and

10 (B) by adding at the end the following:

11 “(4) RULE OF CONSTRUCTION.—Paragraph (2)
12 (regarding waivers) applies to the same extent and
13 in the same manner to assessments required under
14 each of subclauses (I) and (II) of paragraph
15 (1)(A)(i) and assessments required under each of
16 clauses (i) and (ii) of paragraph (1)(B), respec-
17 tively.”;

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

20 “(2) the drug or biological product is in a class
21 of products, is for an indication, or is directed at a
22 specific molecular target in an adult cancer and such
23 molecular target is germane to the growth or pro-
24 gression of cancer in a pediatric cancer, for which
25 there is need for additional options.”; and

1 (4) by adding at the end the following:

2 “(m) LIST OF PRIMARY MOLECULAR TARGETS.—

3 “(1) IN GENERAL.—Within one year of the date
4 of enactment of the FDA Reauthorization Act of
5 2017, the Secretary shall establish and update regu-
6 larly a list of molecular targets considered, on the
7 basis of data the Secretary determines to be ade-
8 quate, to be germane to the growth and progression
9 of a pediatric cancer, and shall publish such list in
10 the Federal Register.

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

13 “(A) consult members of the internal com-
14 mittee under section 505C and the Pediatric
15 Oncology Subcommittee of the Oncologic Drugs
16 Advisory Committee; and

17 “(B) convene a public meeting not later
18 than 1 year after the date of enactment of the
19 FDA Reauthorization Act of 2017 to solicit
20 stakeholder comment on the appropriate con-
21 tents of such list and the data necessary to de-
22 termine that there is scientific evidence that a
23 drug or biological product is directed at a mo-
24 lecular target that is considered, on the basis of
25 data the Secretary determines to be adequate,

1 to be germane to the growth or progression of
2 a pediatric cancer.”.

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

6 “(k) RELATION TO ORPHAN DRUGS.—

7 “(1) IN GENERAL; EXEMPTION FOR ORPHAN IN-
8 DICATIONS.—Unless the Secretary requires other-
9 wise by regulation, except as provided under para-
10 graph (2), this section does not apply to any drug
11 for an indication for which orphan designation has
12 been granted under section 526.

13 “(2) APPLICABILITY DESPITE ORPHAN DES-
14 IGNATION OF CERTAIN CANCER INDICATIONS.—This
15 section shall apply to a drug or biological product
16 has been designated under section 526 for an indica-
17 tion for a pediatric or adult cancer if such drug or
18 biological product is intended for the treatment of
19 an adult cancer and is determined by scientific evi-
20 dence to be directed at a molecular target that is
21 considered, on the basis of data the Secretary deter-
22 mines to be adequate, to be germane to the growth
23 or progression of a pediatric cancer.”.

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

1 Human Services (referred to in this subsection as the
2 “Secretary”), acting through the Commissioner of Food
3 and Drugs and in consultation with the Pediatric Oncol-
4 ogy Advisory Committee of the Food and Drug Adminis-
5 tration, the Director of the National Cancer Institute, and
6 other appropriately identified pediatric oncology experts
7 from both the public and private sectors (including indus-
8 try and academia), shall hold a public meeting, obtain
9 public comment, and issue guidance on the implementa-
10 tion of the amendments to section 505B of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 355e) made by
12 this section, including—

13 (1) the scientific criteria and regulatory consid-
14 erations for determining by scientific evidence
15 whether a drug or biological product indicated for
16 the treatment of an adult cancer is directed at a mo-
17 lecular target germane to the growth or progression
18 of a pediatric cancer;

19 (2) the scientific data, including clinical and
20 preclinical evidence, needed to determine whether a
21 molecular target is germane to the growth or pro-
22 gression of a pediatric cancer;

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

1 (4) how the Secretary will collaborate with pedi-
2 atric networks, academic centers, and experts in pe-
3 diatric oncology to conduct pediatric cancer studies;

4 (5) processes to ensure requirements and
5 timelines are aligned for assessments under sections
6 505A and 505B of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 355a, 355c);

8 (6) scientific and regulatory considerations for
9 study designs, including the applicability of innova-
10 tive regulatory science techniques for pediatric drug
11 developments under such sections 505A and 505B;
12 and

13 (7) considerations for implementation of such
14 section 505B, as so amended, and waivers of the re-
15 quirements of such section 505B with regard to mo-
16 lecular targets for which several drugs or biological
17 products may be under investigation.

18 (d) REPORT TO CONGRESS.—Section 508(b) of the
19 Food and Drug Administration Safety and Innovation Act
20 (21 U.S.C. 355c–1(b)) is amended—

21 (1) in paragraph (10), by striking “; and” and
22 inserting “;”; and

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

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

6 “(12) an assessment of the efforts of the Sec-
7 retary to implement the plan developed under sec-
8 tion 505C-1 of the Federal Food, Drug, and Cos-
9 metic Act, regarding earlier submission of pediatric
10 studies under sections 505A and 505B of such Act
11 and section 351(m) of the Public Health Service
12 Act, including—

13 “(A) the average length of time after the
14 approval of an application under section
15 505(b)(1) of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 355(b)(1)) or section
17 351(a) of the Public Health Service Act (42
18 U.S.C. 262(a)) before studies conducted pursu-
19 ant to such section 505A, 505B, or section
20 351(m) are completed, submitted, and incor-
21 porated into labeling;

22 “(B) the average length of time after the
23 receipt of a proposed pediatric study request be-
24 fore the Secretary responds to such request;

1 “(C) the average length of time after the
2 submission of a proposed pediatric study re-
3 quest before the Secretary issues a written re-
4 quest for such studies;

5 “(D) the number of written requests issued
6 for each investigational new drug or biological
7 product prior to the submission of an applica-
8 tion under section 505(b)(1) of the Federal
9 Food, Drug, and Cosmetic Act or section
10 351(a) of the Public Health Service Act; and

11 “(E) the average number, and range of
12 numbers, of amendments to written requests
13 issued;

14 “(13) a list of sponsors of applications or hold-
15 ers of approved applications who received exclusivity
16 under such section 505A or such section 351(m)
17 after receiving a letter issued under such section
18 505B(d)(1) and before the studies referred to in
19 such letter were completed and submitted;

20 “(14) a list of assessments required under sub-
21 section (a)(2)(A)(i)(II), (b)(1)(A)(i)(II), and
22 (b)(1)(B)(ii) of such section 505B; and

23 “(15) the Secretary’s assessment of the overall
24 impact of the amendments made by section 505 of
25 the FDA Reauthorization Act of 2017 on the con-

1 duct and effectiveness of pediatric cancer research
2 and the Secretary's subsequent recommendations,
3 taking into account the report described in section
4 505(g) of the FDA Reauthorization Act of 2017.”.

5 (e) **RULE OF CONSTRUCTION.**—Nothing in this sec-
6 tion, including the amendments made by this section, shall
7 limit the authority of the Secretary of Health and Human
8 Services to issue written requests under section 505A of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 355a) or section 351(m) of the Public Health Service Act
11 (42 U.S.C. 262(m)).

12 (f) **PROVIDING CERTAINTY REGARDING PEDIATRIC**
13 **STUDY PLANS.**—Section 505B(e) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 355e(e)) is amend-
15 ed—

16 (1) in paragraph (3)—

17 (A) by striking “Not later” and inserting
18 the following:

19 “(A) **IN GENERAL.**—Not later”; and

20 (B) by adding at the end the following:

21 “(B) **CHANGES TO AGREEMENT.**—An
22 agreement documented and confirmed as de-
23 scribed in subparagraph (A) shall not be
24 changed with respect to a specific agreed study
25 after such study begins, except—

1 “(i) with the written agreement of the
2 applicant; or

3 “(ii) pursuant to a written decision by
4 the director of the reviewing division, that
5 a substantial scientific issue essential to
6 determining the adequacy of the pediatric
7 assessments has been identified after such
8 specific agreed study has begun, provided
9 that the Secretary provides the applicant
10 an opportunity for a meeting at which the
11 director and the applicant will be present
12 and at which the director will document
13 the scientific issue involved.”; and

14 (2) in paragraph (5), by striking the first sen-
15 tence and inserting “Subject to paragraph (3), at
16 the initiative of the Secretary or the applicant, the
17 agreed initial pediatric study plan may be amend-
18 ed.”; and

19 (3) in paragraph (6), by inserting “under para-
20 graph (5)” before the period at the end.

21 (g) GAO REPORT.—

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

1 diatric assessments described in subsections
2 (a)(2)(A)(i)(II), (b)(1)(A)(i)(II) and (b)(1)(B)(ii) of
3 section 505B of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355c), as amended by this sec-
5 tion, in the development of drugs and biological
6 products for pediatric cancer indications. The Comp-
7 roller General shall examine—

8 (A) the indications studied in pediatric as-
9 sessments required for drugs or biological prod-
10 ucts intended for the treatment of an adult can-
11 cer;

12 (B) the number of pediatric cancer indica-
13 tions for which assessments have been required
14 under subsections (a)(2)(A)(i)(II),
15 (b)(1)(A)(i)(II), and (b)(1)(B)(ii) of such sec-
16 tion 505B;

17 (C) the number of requests for deferral
18 and waiver of pediatric assessments required
19 under such subsections and the number of such
20 deferral and waiver requests granted and de-
21 nied;

22 (D) the number of orphan-designated indi-
23 cations for drugs and biological products for
24 which assessments were required under such
25 subsections;

1 (E) the number of drugs and biological
2 products approved for the treatment of cancer
3 in the pediatric population for which the sup-
4 portive studies were required to be conducted
5 under such subsections; and

6 (F) any additional considerations by the
7 Secretary regarding the effectiveness of requir-
8 ing pediatric assessments described in sub-
9 sections (a)(2)(A)(i)(II), (b)(1)(A)(i)(II) and
10 (b)(1)(B)(ii) of such section 505B of the in the
11 development of drugs and biological products
12 for pediatric cancer indications.

13 (2) REPORT.—Not later than the date that is
14 6 years after the date of enactment of this Act, the
15 Comptroller General of the United States shall sub-
16 mit a report containing the results of the study
17 under paragraph (1) to the Secretary of Health and
18 Human Services, the Committee on Health, Edu-
19 cation, Labor, and Pensions of the Senate, and the
20 Committee on Energy and Commerce of the House
21 of Representatives.

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:

1 At the appropriate place, insert the following:

2 **SEC. ____ . GUIDANCE REGARDING BIOEQUIVALENCE.**

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

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

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

1 (b) DEADLINE FOR ISSUING GUIDANCE.—The Sec-
2 retary of Health and Human Services, acting through the
3 Commissioner of Food and Drugs, shall publish a guid-
4 ance for each complex non-biologic drug that is approved
5 under section 505(b) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355(b)). Such guidance shall be pub-
7 lished not less than 2 years prior to the earliest date on
8 which an abbreviated new drug application may be sub-
9 mitted pursuant to section 505(j) of the Federal, Food,
10 Drug, and Cosmetic Act (21 U.S.C. 355(c)) that ref-
11 erences such drug.

12 (c) APPLICABILITY.—This section applies to guid-
13 ances whose deadline would be on or after October 1,
14 2017, based on subsection (b).

Susan M. Collins
S.L.C.

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:

1 At the end, add the following:

2 **TITLE IX—GENERIC DRUG**
3 **ACCESS**

4 **Subtitle A—Removing Regulatory**
5 **Barriers to Competition**

6 **SEC. 901. IMPROVING ACCESS TO GENERIC DRUGS.**

7 Section 505(j) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355(j)) is amended by adding at the
9 end the following:

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

1 mission of, an original abbreviated new drug application
2 submitted for review under this subsection, or on a supple-
3 ment to such an application, that is for a drug—

4 “(i) for which there are not more than 3 ap-
5 proved drugs listed under paragraph (7), except that
6 the review of an application submitted more than 30
7 months in advance of the last applicable expiration
8 date for a patent for which a certification under
9 paragraph (2)(A)(vii)(III) has been submitted, or of
10 the expiration date for an applicable period of exclu-
11 sivity under this Act, will not be expedited; or

12 “(ii) that has been included on the list under
13 section 506E.

14 “(B) The Secretary shall require the applicant, not
15 later than 60 days prior to the submission of an applica-
16 tion described in subparagraph (A), to provide complete,
17 accurate information regarding facilities involved in manu-
18 facturing processes and testing, including facilities in cor-
19 responding Type II active pharmaceutical ingredients drug
20 master files submitted with an application and sites or or-
21 ganizations involved in bioequivalence and clinical studies
22 used to support the application, in order to make a deter-
23 mination regarding whether an inspection of an establish-
24 ment is necessary.

1 “(C) The Secretary may expedite an inspection or re-
2 inspection under section 704 of an establishment that pro-
3 poses to manufacture a drug described in subparagraph
4 (A).

5 “(D) Nothing in this paragraph shall prevent the Sec-
6 retary from prioritizing the review of other applications
7 as the Secretary determines appropriate.

8 “(12) The Secretary shall provide review status up-
9 dates to applicants regarding applications under this sub-
10 section, as appropriate, including when the application is
11 awaiting final regulatory action by the office charged with
12 review.

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

18 **SEC. 902. REPORTING ON PENDING GENERIC DRUG APPLI-**
19 **CATIONS, PRIORITY REVIEW APPLICATIONS,**
20 **AND INSPECTIONS.**

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

1 “Secretary”) shall post on the Internet website of the
2 Food and Drug Administration a report that provides—

3 (1) the number of applications filed under sec-
4 tion 505(j) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 355(j)) awaiting action by the appli-
6 cant, including such applications that were filed
7 prior to October 1, 2014;

8 (2) the number of applications filed under sec-
9 tion 505(j) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 355(j)) awaiting action by the Sec-
11 retary, including such applications that were filed
12 prior to October 1, 2014;

13 (3) the number of applications filed under sec-
14 tion 505(j) of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 355(j)) and prior approval supple-
16 ments withdrawn in each month covered by the re-
17 port;

18 (4) the mean and median approval and ten-
19 tative approval times for applications covered by the
20 report;

21 (5) the number of applications described in
22 paragraphs (1), (2), and (3) that are subject to pri-
23 ority review; and

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

1 506H(b) of the Federal Food, Drug, and Cosmetic
2 Act, as added by section 901.

3 (b) ANNUAL REPORT ON PRIORITY REVIEW APPLI-
4 CATIONS.—

5 (1) IN GENERAL.—The Secretary shall submit
6 to the Committee on Health, Education, Labor, and
7 Pensions and the Special Committee on Aging of the
8 Senate and the Committee on Energy and Com-
9 merce of the House of Representatives an annual re-
10 port, not later than March 31 of each year, on the
11 following:

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

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

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

1 Cosmetic Act (21 U.S.C. 355(j)) that are sub-
2 ject to priority review during the most recent
3 calendar year and have been approved by the
4 Secretary.

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

7 (i) for which there are not more than
8 3 approved drugs listed under section
9 505(j)(7) of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 355(j)(7)); and

11 (ii) the number of such applications
12 that are for a drug on the drug shortage
13 list under section 506E of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C.
15 356e).

16 (c) ANNUAL REPORT ON INSPECTIONS.—Not later
17 than March 1 of each year, the Secretary shall post on
18 the Internet website of the Food and Drug Administra-
19 tion—

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

1 (A) approval of a drug under section 505
2 of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 355);

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

6 (C) clearance of a device under section
7 510(k) of such Act (21 U.S.C. 360(k)); and

8 (2) the average and median amount of time to
9 schedule and complete for-cause inspections of facili-
10 ties of drugs and devices.

11 **Subtitle B—Incentivizing** 12 **Competition**

13 **SEC. 911. EXPEDITING GENERIC COMPETITION.**

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

17 **“SEC. 506H. EXPEDITING GENERIC DRUG DEVELOPMENT.**

18 “(a) IN GENERAL.—The Secretary shall, at the re-
19 quest of an applicant, expedite the development and review
20 of an application under subsection (j) of section 505 for
21 a drug—

22 “(1) for which there are not more than 3 ap-
23 proved drug products listed under section 505(j)(7);

24 or

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

3 “(b) REQUEST FROM SPONSORS.—A request to expedite the development and review of an application under
4 subsection (a) shall be submitted by the applicant prior
5 to the submission of such application.
6

7 “(c) OTHER APPLICATIONS.—Nothing in this section
8 shall prevent the Secretary from expediting the development and review of other applications as the Secretary determines appropriate.
9
10

11 “(d) ADDITIONAL COMMUNICATION.—The Secretary
12 shall take such actions as are appropriate to expedite the
13 development and review of the application for approval of
14 a drug described in subsection (a), including, as appropriate—
15

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

19 “(2) providing timely advice to, and interactive
20 communication with, the sponsor regarding the development of the application to ensure that the collection of nonclinical and clinical data necessary for
21 approval is as efficient as practicable;
22
23

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

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

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

8 “(e) REPORTING REQUIREMENT.—A sponsor of a
9 drug expedited under this section shall report to the Sec-
10 retary, one year following approval of an application under
11 section 505(j), on whether the approved drug has been
12 marketed in interstate commerce since approval.”

13 **SEC. 912. LIST OF GENERIC DRUGS WITH LIMITED COM-**
14 **PETITION.**

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

18 **“SEC. 506I. DRUG LISTING.**

19 “(a) REMOVAL, WITHDRAWAL, OR TRANSFER.—The
20 holder of an application approved under subsection (b) or
21 (j) of section 505 shall notify the Secretary within 180
22 days of removing the drug that is the subject of such ap-
23 plication from interstate commerce, withdrawing such ap-
24 proved application, or transferring such approved applica-
25 tion, and a reason for such removal, withdrawal, or trans-

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

6 “(b) DRUGS WITH LIMITED COMPETITION.—

7 “(1) INFORMATION.—The Secretary shall—

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

10 “(B) publish on the Internet website of the
11 Food and Drug Administration such informa-
12 tion under subparagraph (A) with respect to
13 drugs for which there are 3 or fewer application
14 holders; and

15 “(C) update the information published pur-
16 suant to subparagraph (B) every 180 days.

17 “(2) CONTENTS.—The public information main-
18 tained and published under paragraph (1)(B) shall
19 include—

20 “(A) the name of the drug, name of the
21 holder of the approved application, and the
22 marketing status for each drug; and

23 “(B) an indication of whether the Sec-
24 retary considers the drug to be for the treat-
25 ment or prevention of a serious disease or med-

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

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

10 “(d) NOTIFICATION.—When the Secretary first pub-
11 lishes the information under subsection (b), the Secretary
12 shall notify relevant Federal agencies, including the Cen-
13 ters for Medicare & Medicaid Services and the Federal
14 Trade Commission, that the information has been pub-
15 lished and will be updated regularly.”.

16 **SEC. 913. SUITABILITY PETITIONS.**

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

1 (b) REPORT.—The Secretary of Health and Human
2 Services shall include in the annual reports under section
3 902(b)—

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

7 (2) the number of such petitions pending a sub-
8 stantive response for more than 180 days from the
9 date of receipt.

10 **SEC. 914. INSPECTIONS.**

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

14 “(14) If the Secretary issues feedback pursuant to
15 section 704(b)(2) with respect to information submitted
16 in response to a report under section 704(b)(1), and a re-
17 port that was issued under section 704(b)(1) is the only
18 obstacle to approval of an application under this sub-
19 section or the Secretary determines that the public health
20 benefit of approving an application under this subsection
21 outweighs any risk to public health, the Secretary shall,
22 within 45 days of notification by the applicant that nec-
23 essary changes have been made to the establishment to
24 address any findings or deficiencies identified previously
25 by the Secretary—

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

3 “(B) make a determination regarding the re-
4 sponse to such report and review of such applica-
5 tion.”.

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:

- 1 At the appropriate place, insert the following:
- 2 **SEC. ____ . EXPANDED ACCESS.**
- 3 (a) **PATIENT ACCESS TO EXPERIMENTAL TREAT-**
- 4 **MENTS.—**
- 5 (1) **PUBLIC MEETING.—**
- 6 (A) **IN GENERAL.—**The Secretary of
- 7 Health and Human Services (referred to in this
- 8 section as the “Secretary”), acting through the
- 9 Commissioner of Food and Drugs, in coordina-
- 10 tion with the Director of the National Institutes

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

11 (B) TOPICS.—The Secretary shall provide
12 a publicly available report on the topics dis-
13 cussed at the meeting described in subpara-
14 graph (A) within 30 days of such meeting. Such
15 topics shall include discussion of—

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

19 (ii) how patient populations most like-
20 ly to be affected by a drug can benefit
21 from the results of trials that employ alter-
22 native designs, as well as potential risks
23 associated with alternative clinical trial de-
24 signs;

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

2
3 (I) information regarding any potential risks and benefits of participation;
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5

6 (II) regulatory, geographical, and socioeconomic barriers; and
7

8 (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;
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14 (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
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19 (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
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1 and effectiveness is not hindered through
2 potential changes in eligibility criteria.

3 (2) REPORT.—Not later than 1 year after the
4 Secretary issues a report on the topics discussed at
5 the public meeting under paragraph (1)(B), the
6 Comptroller General of the United States shall re-
7 port to the Committee on Health, Education, Labor,
8 and Pensions of the Senate and the Committee on
9 Energy and Commerce of the House of Representa-
10 tives on individual access to investigational drugs
11 through the expanded access program under section
12 561(b) of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 360bbb(b)). The report shall include—

14 (A) a description of actions taken by man-
15 ufacturers under section 561A of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C.
17 360bbb-0);

18 (B) consideration of whether Form FDA
19 3926 and the guidance document entitled “Ex-
20 panded Access to Investigational Drugs for
21 Treatment Use—Questions and Answers”,
22 issued by the Food and Drug Administration in
23 June 2016, has reduced application burden
24 with respect to individuals and physicians seek-
25 ing access to investigational new drugs pursu-

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

5 (C) consideration of whether the guidance
6 or regulations released or updated under section
7 561 of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 360bbb) have improved access
9 for individual patients who do not qualify for
10 clinical trials of such investigational drugs, and
11 what barriers to such access remain;

12 (D) an assessment of how patients and
13 health care providers navigate different avenues
14 to engage with the Food and Drug Administra-
15 tion or drug sponsors on expanded access; and

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

18 (3) GUIDANCE.—

19 (A) IN GENERAL.—Not later than 180
20 days after the publication of the report under
21 paragraph (1), the Secretary, acting through
22 the Commissioner of Food and Drugs, shall
23 issue one or more draft guidances regarding eli-
24 gibility criteria for clinical trials. Not later than
25 18 months after the public comment period on

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

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

9 (i) broaden eligibility criteria for clin-
10 ical trials, especially with respect to drugs
11 for the treatment of serious and life-threat-
12 ening conditions or diseases for which
13 there is an unmet medical need; and

14 (ii) develop eligibility criteria for, and
15 increase trial recruitment to, clinical trials
16 so that enrollment in such trials more ac-
17 curately reflects the patients most likely to
18 receive the drug, as applicable and as ap-
19 propriate, while supporting findings of sub-
20 stantial evidence of safety and effective-
21 ness.

22 (b) IMPROVING INSTITUTIONAL REVIEW BOARD RE-
23 VIEW OF SINGLE PATIENT EXPANDED ACCESS PRO-
24 TOCOL.—Not later than 1 year after the date of enactment
25 of this Act, the Secretary, acting through the Commis-

1 sioner of Food and Drugs, shall issue guidance or regula-
2 tions, or revise existing guidance or regulations, to stream-
3 line the institutional review board review for individual pe-
4 diatric and adult patient expanded access protocol under
5 561(b) of the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 360bbb(b)). Such guidance or regulation may in-
7 clude a description of the conditions under which an insti-
8 tutional review board chair (or designee) may review indi-
9 vidual patient expanded access protocol submitted under
10 section 505(i) of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 355(i)) for a drug and how centralized in-
12 stitutional review boards may facilitate the use of ex-
13 panded access protocols. The Secretary shall update any
14 relevant forms associated with individual patient expanded
15 access protocol as necessary.

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

19 (1) in the matter preceding paragraph (1), by
20 striking “later” and inserting “earlier”;

21 (2) by striking paragraph (1);

22 (3) by redesignating paragraph (2) as para-
23 graph (1);

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

4 (5) by adding at the end the following:

5 “(2) as applicable, 15 days after the drug re-
6 ceives a designation as a breakthrough therapy, fast
7 track product, or regenerative advanced therapy
8 under subsection (a), (b), or (g), respectively, of sec-
9 tion 506.”.

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:

- 1 At the appropriate place, insert the following:
- 2 **SEC. ____ . EXTENSION OF EXCLUSIVITY PERIODS FOR A**
- 3 **DRUG APPROVED FOR A NEW INDICATION**
- 4 **FOR A RARE DISEASE OR CONDITION.**
- 5 (a) IN GENERAL.—The Federal Food, Drug, and
- 6 Cosmetic Act is amended by inserting after section 505F
- 7 of such Act (21 U.S.C. 355g) the following:

1 **“SEC. 505G. EXTENSION OF EXCLUSIVITY PERIODS FOR A**
2 **DRUG APPROVED FOR A NEW INDICATION**
3 **FOR A RARE DISEASE OR CONDITION.**

4 “(a) DESIGNATION.—

5 “(1) IN GENERAL.—The Secretary shall des-
6 ignate a drug as a drug approved for a new indica-
7 tion to prevent, diagnose, or treat a rare disease or
8 condition for purposes of granting the extensions
9 under subsection (b) if—

10 “(A) prior to approval of an application or
11 supplemental application for the new indication,
12 the drug was approved or licensed under section
13 505(c) of this Act or section 351(a) of the Pub-
14 lic Health Service Act but was not so approved
15 or licensed for the new indication;

16 “(B)(i) the sponsor of the approved or li-
17 censed drug files an application or a supple-
18 mental application for approval of the new indi-
19 cation for use of the drug to prevent, diagnose,
20 or treat the rare disease or condition; and

21 “(ii) the Secretary approves the application
22 or supplemental application; and

23 “(C) the application or supplemental appli-
24 cation for the new indication contains the con-
25 sent of the applicant to public notice under

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

3 “(2) REVOCATION OF DESIGNATION.—

4 “(A) IN GENERAL.—Except as provided in
5 subparagraph (B), a designation under para-
6 graph (1) shall not be revoked for any reason.

7 “(B) EXCEPTION.—The Secretary may re-
8 voke a designation of a drug under paragraph
9 (1) if the Secretary finds that the application or
10 supplemental application resulting in such des-
11 ignation contained an untrue statement of ma-
12 terial fact.

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

16 “(b) EXTENSION.—

17 “(1) IN GENERAL.—If the Secretary designates
18 a drug as a drug approved for a new indication for
19 a rare disease or condition, as described in sub-
20 section (a)(1)—

21 “(A)(i) the 4-, 5-, and 7¹/₂-year periods de-
22 scribed in subsections (c)(3)(E)(ii) and
23 (j)(5)(F)(ii) of section 505, the 3-year periods
24 described in clauses (iii) and (iv) of subsection
25 (c)(3)(E) and clauses (iii) and (iv) of subsection

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

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

9 “(B)(i) if the drug is the subject of a listed
10 patent for which a certification has been sub-
11 mitted under subsection (b)(2)(A)(ii) or
12 (j)(2)(A)(vii)(II) of section 505 or a listed pat-
13 ent for which a certification has been submitted
14 under subsections (b)(2)(A)(iii) or
15 (j)(2)(A)(vii)(III) of section 505, the period
16 during which an application may not be ap-
17 proved under section 505(c)(3) or section
18 505(j)(5)(B) shall be extended by a period of 6
19 months after the date the patent expires (in-
20 cluding any patent extensions); or

21 “(ii) if the drug is the subject of a listed
22 patent for which a certification has been sub-
23 mitted under subsection (b)(2)(A)(iv) or
24 (j)(2)(A)(vii)(IV) of section 505, and in the pat-
25 ent infringement litigation resulting from the

1 certification the court determines that the pat-
2 ent is valid and would be infringed, the period
3 during which an application may not be ap-
4 proved under section 505(c)(3) or section
5 505(j)(5)(B) shall be extended by a period of 6
6 months after the date the patent expires (in-
7 cluding any patent extensions).

8 “(2) RELATION TO PEDIATRIC AND QUALIFIED
9 INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any
10 extension under paragraph (1) of a period shall be
11 in addition to any extension of the periods under
12 sections 505A and 505E of this Act and section
13 351(m) of the Public Health Service Act, as applica-
14 ble, with respect to the drug.

15 “(c) LIMITATIONS.—Any extension described in sub-
16 section (b)(1) shall not apply if the drug designated under
17 subsection (a)(1) has previously received an extension by
18 operation of subsection (b)(1).

19 “(d) DEFINITION.—In this section, the term ‘rare
20 disease or condition’ has the meaning given to such term
21 in section 526(a)(2).”.

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

1 (a)(1)(B)(i) of such section 505G is first approved under
2 section 505(c) of such Act (21 U.S.C. 355(c)) or section
3 351(a) of the Public Health Service Act (42 U.S.C.
4 262(a)) between the date of enactment of this Act and
5 the date that is 7 years after such date of enactment.

6 (c) CONFORMING AMENDMENTS.—

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

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

12 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
13 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
14 EASE OR CONDITION.—Notwithstanding the ref-
15 erences in paragraph (1) to the lengths of the exclu-
16 sivity periods after application of pediatric exclu-
17 sivity, the 6-month extensions described in para-
18 graph (1) shall be in addition to any extensions
19 under section 505G.”; and

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

22 “(3) RELATION TO EXCLUSIVITY FOR A DRUG
23 APPROVED FOR A NEW INDICATION FOR A RARE DIS-
24 EASE OR CONDITION.—Notwithstanding the ref-
25 erences in paragraph (1) to the lengths of the exclu-

1 sivity periods after application of pediatric exclu-
2 sivity, the 6-month extensions described in para-
3 graph (1) shall be in addition to any extensions
4 under section 505G.”.

5 (2) RELATION TO EXCLUSIVITY FOR NEW
6 QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT
7 ARE DRUGS.—Subsection (b) of section 505E of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 355f) is amended—

10 (A) by amending the subsection heading to
11 read as follows: “RELATION TO PEDIATRIC EX-
12 CLUSIVITY AND EXCLUSIVITY FOR A DRUG AP-
13 PROVED FOR A NEW INDICATION FOR A RARE
14 DISEASE OR CONDITION.—”; and

15 (B) by striking “any extension of the pe-
16 riod under section 505A” and inserting “any
17 extension of the periods under sections 505A
18 and 505G, as applicable,”.

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

23 “(5) RELATION TO EXCLUSIVITY FOR A BIO-
24 LOGICAL PRODUCT APPROVED FOR A NEW INDICA-
25 TION FOR A RARE DISEASE OR CONDITION.—Not-

1 withstanding the references in paragraphs (2)(A),
2 (2)(B), (3)(A), and (3)(B) to the lengths of the ex-
3 clusivity periods after application of pediatric exclu-
4 sivity, the 6-month extensions described in such
5 paragraphs shall be in addition to any extensions
6 under section 505G.”.

7 (d) GAO REPORT.—

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

12 (A) the extent to which this Act, including
13 the amendments made by this Act, provides tar-
14 geted incentives to develop, and increased avail-
15 ability to, safe and effective treatments for rare
16 diseases and conditions, and recommendations
17 for expanding such availability;

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

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

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

3 (ii) to the extent practicable, the ex-
4 tent to which rebates and other price con-
5 cessions reduce the cost of such drug; and

6 (iii) to the extent practicable, the ex-
7 tent to which such drug contributes to re-
8 duced health care costs through prevention
9 or reduced use of hospital and other health
10 care services; and

11 (C) whether there are barriers to indica-
12 tion-based pricing or value-based pricing for
13 manufacturers of drugs designated under sec-
14 tion 526 of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 360bb) as drugs for a
16 rare disease or condition.

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

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

4 (1) in subsection (a), in the matter following
5 paragraph (2), by striking “such drug for such dis-
6 ease or condition” and inserting “the same drug for
7 the same disease or condition”;

8 (2) in subsection (b)—

9 (A) in the matter preceding paragraph (1),
10 by striking “If an application” and all that fol-
11 lows through “such license if” and inserting
12 “During the 7-year period described in sub-
13 section (a) for an approved application under
14 section 505 or license under section 351 of the
15 Public Health Service Act, the Secretary may
16 approve an application or issue a license for a
17 drug that is otherwise the same, as determined
18 by the Secretary, as the already approved drug
19 for the same rare disease or condition if”;

20 (B) in paragraph (1), by striking “notice”
21 and all that follows through “assure” and in-
22 serting “of exclusive approval or licensure no-
23 tice and opportunity for the submission of
24 views, that during such period the holder of the

1 exclusive approval or licensure cannot ensure”;
2 and

3 (C) in paragraph (2), by striking “such
4 holder provides” and inserting “the holder pro-
5 vides”; and

6 (3) by adding at the end the following:

7 “(c) CONDITION OF CLINICAL SUPERIORITY.—

8 “(1) IN GENERAL.—If a sponsor of a drug that
9 is designated under section 526 and is otherwise the
10 same, as determined by the Secretary, as an already
11 approved or licensed drug is seeking exclusive ap-
12 proval or exclusive licensure described in subsection
13 (a) for the same rare disease or condition as the al-
14 ready approved drug, the Secretary shall require
15 such sponsor, as a condition of such exclusive ap-
16 proval or licensure, to demonstrate that such drug is
17 clinically superior to any already approved or li-
18 censed drug that is the same drug.

19 “(2) DEFINITION.—For purposes of paragraph
20 (1), the term ‘clinically superior’ with respect to a
21 drug means that the drug provides a significant
22 therapeutic advantage over and above an already ap-
23 proved or licensed drug in terms of greater efficacy,
24 greater safety, or by providing a major contribution
25 to patient care.

1 “(d) REGULATIONS.—The Secretary may promulgate
2 regulations for the implementation of subsection (c). Until
3 such time as the Secretary promulgates regulations in ac-
4 cordance with this subsection, any definitions set forth in
5 regulations implementing this section that were promul-
6 gated prior to the date of enactment of the FDA Reau-
7 thorization Act of 2017 shall continue to apply.”.



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.

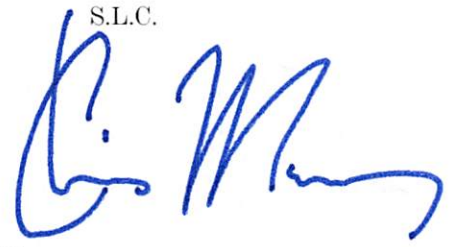
Referred to the Committee on Health, Education, Labor and Pensions and ordered to be printed

Ordered to lie on the table and to be printed

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

Viz:

- 1 At the appropriate place, insert the following:
- 2 **SEC. ____ . PROTECTION OF ESSENTIAL HEALTH BENEFITS.**
- 3 Notwithstanding any other provision of law, no waiv-
- 4 er or exception may be provided to any State with respect
- 5 to the inclusion in health insurance coverage of the core
- 6 package of 10 essential health benefits as defined by the
- 7 Secretary of Health and Human Services under section
- 8 1302 of the Patient Protection and Affordable Care Act
- 9 (42 U.S.C. 18022).



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

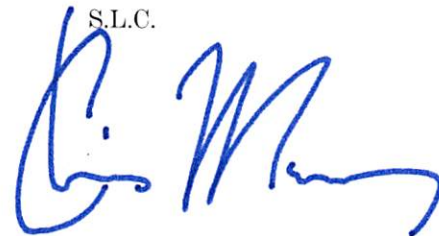
AMENDMENT intended to be proposed by Mr. Murphy, Ms. Baldwin, Ms. Warren

Viz:

1 At the appropriate place, insert the following:

2 **SEC. ____ . MENTAL HEALTH AND SUBSTANCE USE DIS-**
3 **ORDER SERVICES.**

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


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

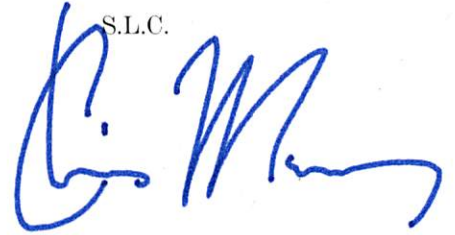
AMENDMENT intended to be proposed by Mr. Murphy, Ms. Baldwin, Ms. Warren

Viz:

1 At the appropriate place, insert the following:

2 **SEC. ____ . NO WAIVER FROM AGE-RATING BANDS.**

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



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:

1 At the appropriate place, insert the following:

2 **SEC. ____ . PROTECTING INDIVIDUALS WITH PRE-EXISTING**
3 **CONDITIONS.**

4 Notwithstanding any other provision of law, there
5 shall be no waiver granted from the requirements of sec-
6 tions 2701 and 2705(b) of the Public Health Service Act
7 (42 U.S.C. 300gg and 300gg-4(b)).

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:

- 1 On page 88, line 18, strike “section 312.47(b)” and
- 2 insert “section 312.82(b)”.

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:

1 At the end of section 202, add the following:

2 (5) by amending subparagraph (J) of para-
3 graph (9) (as redesignated by paragraph (1)) to
4 read as follows:

5 “(J) Evaluation of postmarket studies re-
6 quired as a condition of an approval of a pre-
7 market application or premarket report under
8 section 515 or a premarket application under
9 section 351 of the Public Health Service Act
10 and supporting pilot projects under section
11 519(i).”.

Paul Amdt #1

S.L.C.
[Handwritten Signature]

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:

1 At the appropriate place, insert the following:

2 **SEC. ____ . USE OF CLINICAL INVESTIGATION DATA FROM**
3 **OUTSIDE THE UNITED STATES.**

4 Section 569B of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 360bbb-8b) is amended—

6 (1) in subsection (a)—

7 (A) by striking “In determining” and in-
8 sserting “Subject to subsection (c), in deter-
9 mining”;

1 (B) by inserting “or section 351 of the
2 Public Health Service Act” after “this chap-
3 ter”; and

4 (C) by striking “, including the European
5 Union, if the applicant demonstrates that such
6 data are” and inserting “unless the Secretary
7 determines the data is not”;

8 (2) in subsection (b), by striking “, including in
9 the European Union,”; and

10 (3) by adding at the end the following:

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

13 “(1) IN GENERAL.—In the case of an applica-
14 tion for approval or clearance of a drug, biological
15 product, or device under this chapter or section 351
16 of the Public Health Service Act where such drug,
17 biological product, or device has been approved in a
18 country described in paragraph (2), within the
19 timelines established in the letters referred to in sec-
20 tion 101(b) of the Prescription Drug User Fee
21 Amendments of 2017 in the case of a drug or within
22 the timelines established in the letters referred to in
23 section 201(b) of the Medical Device User Fee
24 Amendments of 2017 in the case of a device, or such

1 additional period as may be agreed upon by the Sec-
2 retary and the applicant, the Secretary shall—

3 “(A) approve the application, if the Sec-
4 retary finds no grounds for denying approval of
5 the application; or

6 “(B) provide written notice to the sponsor
7 of the application of a finding that is grounds
8 for denying approval, including the rationale for
9 such finding, and provide the sponsor an oppor-
10 tunity for a hearing.

11 “(2) APPLICABLE COUNTRIES.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (B), the countries described in this para-
14 graph are—

15 “(i) Australia;

16 “(ii) Austria;

17 “(iii) Belgium;

18 “(iv) Canada;

19 “(v) Chile;

20 “(vi) Czech Republic;

21 “(vii) Denmark;

22 “(viii) Estonia;

23 “(ix) Finland;

24 “(x) France;


25 “(xi) Germany;

- 1 “(xii) Greece;
- 2 “(xiii) Hungary;
- 3 “(xiv) Iceland;
- 4 “(xv) Ireland;
- 5 “(xvi) Israel;
- 6 “(xvii) Italy;
- 7 “(xviii) Japan;
- 8 “(xix) Korea;
- 9 “(xx) Latvia;
- 10 “(xxi) Luxembourg;
- 11 “(xxii) Mexico;
- 12 “(xxiii) Netherlands;
- 13 “(xxiv) New Zealand;
- 14 “(xxv) Norway;
- 15 “(xxvi) Poland;
- 16 “(xxvii) Portugal;
- 17 “(xxviii) Slovak Republic;
- 18 “(xxix) Slovenia;
- 19 “(xxx) Spain;
- 20 “(xxxi) Sweden;
- 21 “(xxxii) Switzerland;
- 22 “(xxxiii) Turkey; and
- 23 “(xxxiv) United Kingdom.

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

1 the list under subparagraph (A), as the Sec-
2 retary determines appropriate.”.

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:

1 At the appropriate place, add the following:

2 **SEC. ____ . FOOD ADDITIVES.**

3 Section 409(a) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 348(a)) is amended—

5 (1) in paragraph (2), by striking “; or” and in-
6 serting “;”;

7 (2) in paragraph (3)(B), by striking the period
8 and inserting “; or”; and

9 (3) by inserting after paragraph (3) the fol-
10 lowing:

1 “(4) there is in effect a regulation, approval, or
2 other determination issued by one or more developed
3 countries, including a country in the European
4 Union, prescribing the conditions under which such
5 additive may be safely used, and the additive and its
6 use or intended use are in conformity with such reg-
7 ulation, approval, or other determination, unless the
8 Secretary by regulation determines—

9 “(A) the additive is unsafe in its intended
10 use under the conditions prescribed in such reg-
11 ulation, approval, or other determination; or

12 “(B) the regulation, approval, or other de-
13 termination process in a particular country is
14 not capable of prescribing the conditions under
15 which an additive may be safely used.”.

Bob 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:

- 1 At the end of title XVIII, add the following:
- 2 **SEC. 807. IMPORTING AFFORDABLE AND SAFE DRUGS**
- 3 **FROM CANADA.**
- 4 (a) IN GENERAL.—Section 804 of the Federal Food,
- 5 Drug, and Cosmetic Act (21 U.S.C. 384) is amended to
- 6 read as follows:

1 **“SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE**
2 **DRUGS BY WHOLESALE DISTRIBUTORS,**
3 **PHARMACIES, AND INDIVIDUALS.**

4 “(a) IN GENERAL.—Not later than 180 days after
5 the date of enactment of the FDA Reauthorization Act
6 of 2017, the Secretary shall promulgate regulations per-
7 mitting the importation of qualifying prescription drugs
8 into the United States, in accordance with this section.

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

10 “(1) CERTIFIED FOREIGN SELLER.—The term
11 ‘certified foreign seller’ means a licensed foreign
12 pharmacy or foreign wholesale distributor that the
13 Secretary certifies under subsection (d)(1)(B), that
14 pays the fee required under subsection (d)(1)(C),
15 and that is included on the list described in sub-
16 section (c).

17 “(2) FOREIGN WHOLESALE DISTRIBUTOR.—
18 The term ‘foreign wholesale distributor’ means a
19 person (other than a manufacturer, a manufactur-
20 er’s co-licensed partner, a third-party logistics pro-
21 vider, or a repackager) engaged in wholesale dis-
22 tribution.

23 “(3) IMPORTER.—The term ‘importer’ means a
24 dispenser (as defined in section 581(3)) or wholesale
25 distributor registered under section 503(e) who im-

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

3 “(4) LICENSED FOREIGN PHARMACY.—The
4 term ‘licensed foreign pharmacy’ means a pharmacy
5 located in Canada that—

6 “(A) operates in accordance with applica-
7 ble pharmacy standards set forth by the provin-
8 cial pharmacy rules and regulations enacted in
9 Canada; and

10 “(B) is licensed to operate and dispense
11 prescription drugs to individuals in Canada.

12 “(5) QUALIFYING PRESCRIPTION DRUG.—The
13 term ‘qualifying prescription drug’—

14 “(A) means a prescription drug that—

15 “(i) is approved for use in patients,
16 and marketed, in Canada;

17 “(ii) is manufactured in a facility reg-
18 istered under subsection (b)(1) or (i) of
19 section 510 that is in compliance with good
20 manufacturing practices regulations of the
21 Food and Drug Administration;

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

1 paragraph (B)(iv), is biosimilar to an ap-
2 proved biological product and has the same
3 route of administration and strength as the
4 approved biological product; and

5 “(iv) is labeled in accordance with—

6 “(I) the laws of Canada; and

7 “(II) the requirements promul-
8 gated by the Secretary, which shall in-
9 clude labeling in English;

10 “(B) with respect to importers only, in-
11 cludes—

12 “(i) peritoneal dialysis solution;

13 “(ii) insulin;

14 “(iii) a drug for which a risk evalua-
15 tion and mitigation strategy is required
16 under section 505-1;

17 “(iv) biological products, as defined in
18 section 351 of the Public Health Service
19 Act that are proteins (except any chemi-
20 cally synthesized polypeptides) or analo-
21 gous products; and

22 “(v) intravenously infused drugs; and

23 “(C) does not include—

1 “(i) a controlled substance (as defined
2 in section 102 of the Controlled Sub-
3 stances Act);

4 “(ii) an anesthetic drug inhaled dur-
5 ing surgery; or

6 “(iii) a compounded drug.

7 “(6) VALID PRESCRIPTION.—The term ‘valid
8 prescription’ means a prescription that is issued for
9 a legitimate medical purpose in the usual course of
10 professional practice by—

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

14 “(B) a covering practitioner.

15 “(c) PUBLICATION OF CERTIFIED FOREIGN SELL-
16 ERS.—The Secretary shall publish on a dedicated Internet
17 Web site a list of certified foreign sellers, including the
18 Internet Web site address, physical address, and telephone
19 number of each such certified foreign seller.

20 “(d) ADDITIONAL CRITERIA.—

21 “(1) CERTIFIED FOREIGN SELLERS.—

22 “(A) IN GENERAL.—To be a certified for-
23 eign seller, such seller shall—

24 “(i) be certified by the Secretary in
25 accordance with subparagraph (B);

1 “(ii) pay the registration fee estab-
2 lished under subparagraph (C); and

3 “(iii) sell only qualifying prescription
4 drugs to importers or individuals who im-
5 port prescription drugs into the United
6 States in accordance with this section.

7 “(B) CERTIFICATION.—To be a certified
8 foreign seller, the Secretary shall certify that
9 such seller—

10 “(i) is a foreign wholesale distributor
11 or licensed foreign pharmacy operating an
12 establishment, which may include an online
13 foreign pharmacy, that is located in Can-
14 ada;

15 “(ii) is engaged in the distribution or
16 dispensing of a prescription drug that is
17 imported or offered for importation into
18 the United States;

19 “(iii) has been in existence for a pe-
20 riod of at least 5 years preceding the date
21 of such certification and has a purpose
22 other than to participate in the program
23 established under this section;

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

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

5 “(v) has processes established by the
6 seller, or participates in another estab-
7 lished process, to certify that the physical
8 premises and data reporting procedures
9 and licenses are in compliance with all ap-
10 plicable laws and regulations of Canada
11 and has implemented policies designed to
12 monitor ongoing compliance with such laws
13 and regulations;

14 “(vi) conducts or commits to partici-
15 pate in ongoing and comprehensive quality
16 assurance programs and implements such
17 quality assurance measures, including
18 blind testing, to ensure the veracity and re-
19 liability of the findings of the quality as-
20 surance program;

21 “(vii) agrees that, pursuant to sub-
22 section (f), laboratories approved by the
23 Secretary may be authorized to conduct
24 product testing to determine the chemical

1 authenticity of sample pharmaceutical
2 products;

3 “(viii) agrees to notify the Secretary,
4 importers, and individuals of product re-
5 calls in Canada and agrees to cease, or re-
6 frain from, exporting such product;

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

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

17 “(xi) meets any other criteria estab-
18 lished by the Secretary.

19 “(C) CERTIFICATION FEE.—Not later than
20 30 days before the start of each fiscal year, the
21 Secretary shall establish a fee to be collected
22 from foreign sellers for such fiscal year that are
23 certified under subparagraph (B), in an amount
24 that is sufficient, and not more than necessary,
25 to pay the costs of administering the program

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

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

12 “(2) INDIVIDUALS.—An individual may import
13 a qualifying prescription drug described in sub-
14 section (b) from Canada if such drug—

15 “(A) is dispensed, including through an
16 online pharmacy, by a certified foreign seller
17 that is a licensed foreign pharmacy;

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

21 “(C) is filled only after providing to the li-
22 censed foreign pharmacy a valid prescription
23 issued by a health care practitioner licensed to
24 practice in a State in the United States.

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

5 “(f) DRUG TESTING LABORATORIES.—The Secretary
6 may approve one or more laboratories to conduct random
7 testing of prescription drugs sold by certified foreign sell-
8 ers to assess the chemical authenticity of such drugs.

9 “(g) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
10 TICES.—It is unlawful for a manufacturer, directly or indi-
11 rectly (including by being a party to a licensing agreement
12 or other agreement)—

13 “(1) to discriminate by charging a higher price
14 for a prescription drug sold to a certified foreign
15 seller that sells such drug to an importer in accord-
16 ance with this section than the price that is charged,
17 inclusive of rebates or other incentives to the coun-
18 try from which the drug is exported, to another per-
19 son that is in the same country and that does not
20 import such a drug into the United States in accord-
21 ance with this section;

22 “(2) except with respect to a prescription drug
23 on the drug shortage list under section 506E, dis-
24 criminate by denying, restricting, or delaying sup-
25 plies of a prescription drug to a certified foreign sell-

1 er, on account of such seller's status as a certified
2 foreign seller, that sells such drug to an importer in
3 accordance with this section, or by publicly, pri-
4 vately, or otherwise refusing to do business with
5 such a certified foreign seller on account of such
6 seller's status as a certified foreign seller;

7 “(3) cause there to be a difference (including a
8 difference in active ingredient, route of administra-
9 tion, bioequivalence, strength, formulation, manufac-
10 turing establishment, manufacturing process, or per-
11 son that manufactures the drug) between a prescrip-
12 tion drug for distribution in the United States and
13 the drug for distribution in Canada, for the purpose
14 of avoiding sales by certified foreign sellers; or

15 “(4) except with respect to a prescription drug
16 on the drug shortage list under section 506E, en-
17 gage in any other action to restrict, prohibit, or
18 delay the importation of a prescription drug under
19 this section.

20 “(h) INFORMATION AND RECORDS.—

21 “(1) BIENNIAL REPORTS.—Each importer shall
22 submit biennial reports to the Secretary which shall
23 contain, for each qualifying prescription drug im-
24 ported into the United States—

1 “(A) the unique facility identifier of the
2 manufacturer of the drug, described in section
3 510;

4 “(B) the transaction information described
5 in section 581(26) (other than the information
6 described in subparagraph (C)); and

7 “(C) the price paid by the importer for the
8 drug.

9 “(2) MAINTENANCE OF RECORDS BY SEC-
10 RETARY.—The Secretary shall maintain information
11 and documentation submitted under paragraph (1)
12 for such period of time as the Secretary determines
13 to be appropriate.

14 “(i) SUSPENSION OF IMPORTATION.—

15 “(1) PATTERNS OF NONCOMPLIANCE.—The
16 Secretary shall require that importation of a specific
17 qualifying prescription drug or importation by a spe-
18 cific certified foreign seller or importer pursuant to
19 this section be immediately suspended if the Sec-
20 retary determines that there is a pattern of importa-
21 tion of such specific drug or by such specific seller
22 or importer that involves counterfeit drugs, drugs
23 that have been recalled or withdrawn, or drugs in
24 violation of any requirement of this section, until an
25 investigation is completed and the Secretary deter-

1 mines that importation of such drug or by such sell-
2 er or importer does not endanger the public health.

3 “(2) TEMPORARY SUSPENSION.—The Secretary
4 may require that importation of a specific qualifying
5 prescription drug or importation by a specific cer-
6 tified foreign seller or importer pursuant to this sec-
7 tion be temporarily suspended if, with respect to
8 such drug, seller, or importer, there is a violation of
9 any requirement of this section or if the Secretary
10 determines that importation of such drug or by such
11 seller or importer might endanger the public health.
12 Such temporary suspension shall apply until the Sec-
13 retary completes an investigation and determines
14 that importation of such drug or by such seller or
15 importer does not endanger the public health.

16 “(j) SUPPLY CHAIN SECURITY.—

17 “(1) PURCHASE FROM REGISTERED FACILITIES
18 AND CERTIFIED FOREIGN SELLERS.—

19 “(A) IN GENERAL.—Except as provided in
20 subparagraph (B), certified foreign sellers who
21 sell qualifying prescription drugs for importa-
22 tion into the United States pursuant to this
23 section may purchase such drugs only from
24 manufacturers or entities registered under sec-
25 tion 510 or other certified foreign sellers.

1 “(B) EXCEPTION.—Certified foreign sellers
2 who sell qualifying prescription drugs for im-
3 portation into the United States pursuant to
4 this section may purchase such drugs from for-
5 eign sellers in Canada or another permitted
6 country, even if such foreign seller is not a
7 manufacturer registered under section 510 or a
8 certified foreign seller, if the Secretary enters
9 into a memorandum of understanding or coop-
10 erative agreement with Canada, or such other
11 permitted country, to ensure compliance, to the
12 extent appropriate and feasible, with subchapter
13 H of chapter V. The Secretary shall seek to
14 enter into such a memorandum of under-
15 standing or cooperative agreement with Canada.

16 “(2) IMPORTATION TRACING.—Certified foreign
17 sellers shall provide importers with the unique facil-
18 ity identifier associated with the manufacturer reg-
19 istered under section 510 of the qualifying prescrip-
20 tion drug and the information under paragraph
21 (25), paragraph (26) (other than subparagraph (C)),
22 and subparagraphs (D), (F), and (G) of paragraph
23 (27) of section 581. Certified foreign sellers shall
24 provide such information to individuals purchasing
25 such drugs, upon request.

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

10 “(l) CONSTRUCTION.—Nothing in this section limits
11 the authority of the Secretary relating to the importation
12 of prescription drugs, other than with respect to section
13 801(d)(1) as provided in this section.”.

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

18 “(h) In the case of person operating an Internet
19 website, whether in the United States or in another coun-
20 try, that violates section 301(aa) by—

21 “(1) selling, by means of the Internet, with the
22 intent to defraud or mislead or with reckless dis-
23 regard for safety of the public, an adulterated or
24 counterfeit drug to an individual in the United
25 States; or

1 “(2) dispenses, by means of the Internet, a
2 drug to an individual in the United States who the
3 person knows or has reasonable cause to believe,
4 does not possess a valid prescription for that drug,
5 such person shall be imprisoned for not more than
6 10 years or fined not more than \$250,000.”.

7 (c) NO PREEMPTION.—Nothing in this section, in-
8 cluding the amendments made by this section, shall be
9 construed to preempt, alter, displace, abridge, or supplant
10 any remedy available under any State or Federal law, in-
11 cluding common law, that provides a remedy for civil re-
12 lief.

13 (d) REPORTS.—

14 (1) HHS.—Not later than 1 year after the date
15 on which final regulations are promulgated to carry
16 out section 804 of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 384), as amended by this sec-
18 tion, and every 2 years thereafter, the Secretary of
19 Health and Human Services, after consultation with
20 appropriate Federal agencies, shall submit to Con-
21 gress and make public a report on the importation
22 of drugs into the United States.

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

1 Drug, and Cosmetic Act (21 U.S.C. 384), as amend-
2 ed by this section, the Comptroller General of the
3 United States shall submit to Congress a report con-
4 taining an analysis of the implementation of the
5 amendments made by this section, including a review
6 of drug safety and cost-savings and expenses, includ-
7 ing cost-savings to consumers in the United States
8 and trans-shipment and importation tracing proc-
9 esses, resulting from such implementation.

Barack Sanders

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:

1 At the end of title XVIII, add the following:

2 **SEC. 807. IMPORTING AFFORDABLE AND SAFE DRUGS.**

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

6 **“SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE**
7 **DRUGS BY WHOLESALE DISTRIBUTORS,**
8 **PHARMACIES, AND INDIVIDUALS.**

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

1 of 2017, the Secretary shall promulgate regulations per-
2 mitting the importation of qualifying prescription drugs
3 into the United States, in accordance with this section.

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

5 “(1) CERTIFIED FOREIGN SELLER.—The term
6 ‘certified foreign seller’ means a licensed foreign
7 pharmacy or foreign wholesale distributor that the
8 Secretary certifies under subsection (d)(1)(B), that
9 pays the fee required under subsection (d)(1)(C),
10 and that is included on the list described in sub-
11 section (c).

12 “(2) FOREIGN WHOLESALE DISTRIBUTOR.—
13 The term ‘foreign wholesale distributor’ means a
14 person (other than a manufacturer, a manufactur-
15 er’s co-licensed partner, a third-party logistics pro-
16 vider, or a repackager) engaged in wholesale dis-
17 tribution.

18 “(3) IMPORTER.—The term ‘importer’ means a
19 dispenser (as defined in section 581(3)) or wholesale
20 distributor registered under section 503(e) who im-
21 ports prescription drugs into the United States in
22 accordance with this section.

23 “(4) LICENSED FOREIGN PHARMACY.—The
24 term ‘licensed foreign pharmacy’ means a pharmacy

1 located in Canada, or subject to subsection (e), an-
2 other applicable country, that—

3 “(A) operates in accordance with applica-
4 ble pharmacy standards set forth by the provin-
5 cial pharmacy rules and regulations enacted in
6 Canada, or, subject to subsection (e), such ap-
7 plicable rules and regulations of the permitted
8 country in which such seller is located; and

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

13 “(5) QUALIFYING PRESCRIPTION DRUG.—The
14 term ‘qualifying prescription drug’—

15 “(A) means a prescription drug that—

16 “(i) is approved for use in patients,
17 and marketed, in Canada, or subject to
18 subsection (e), approved for use in pa-
19 tients, and marketed, in another permitted
20 country;

21 “(ii) is manufactured in a facility reg-
22 istered under subsection (b)(1) or (i) of
23 section 510 that is in compliance with good
24 manufacturing practices regulations of the
25 Food and Drug Administration;

1 “(iii) has the same active ingredient
2 or ingredients, route of administration, and
3 strength as a prescription drug approved
4 under chapter V, or, for purposes of sub-
5 paragraph (B)(iv), is biosimilar to an ap-
6 proved biological product and has the same
7 route of administration and strength as the
8 approved biological product; and

9 “(iv) is labeled in accordance with—

10 “(I) the laws of Canada, or an-
11 other country from which importation
12 is permitted pursuant to subsection
13 (e); and

14 “(II) the requirements promul-
15 gated by the Secretary, which shall in-
16 clude labeling in English;

17 “(B) with respect to importers only, in-
18 cludes—

19 “(i) peritoneal dialysis solution;

20 “(ii) insulin;

21 “(iii) a drug for which a risk evalua-
22 tion and mitigation strategy is required
23 under section 505-1;

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

1 Act that are proteins (except any chemi-
2 cally synthesized polypeptides) or analo-
3 gous products; and

4 “(v) intravenously infused drugs; and

5 “(C) does not include—

6 “(i) a controlled substance (as defined
7 in section 102 of the Controlled Sub-
8 stances Act);

9 “(ii) an anesthetic drug inhaled dur-
10 ing surgery; or

11 “(iii) a compounded drug.

12 “(6) VALID PRESCRIPTION.—The term ‘valid
13 prescription’ means a prescription that is issued for
14 a legitimate medical purpose in the usual course of
15 professional practice by—

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

19 “(B) a covering practitioner.

20 “(c) PUBLICATION OF CERTIFIED FOREIGN SELL-
21 ERS.—The Secretary shall publish on a dedicated Internet
22 Web site a list of certified foreign sellers, including the
23 Internet Web site address, physical address, and telephone
24 number of each such certified foreign seller.

25 “(d) ADDITIONAL CRITERIA.—

1 “(1) CERTIFIED FOREIGN SELLERS.—

2 “(A) IN GENERAL.—To be a certified for-
3 eign seller, such seller shall—

4 “(i) be certified by the Secretary in
5 accordance with subparagraph (B);

6 “(ii) pay the registration fee estab-
7 lished under subparagraph (C); and

8 “(iii) sell only qualifying prescription
9 drugs to importers or individuals who im-
10 port prescription drugs into the United
11 States in accordance with this section.

12 “(B) CERTIFICATION.—To be a certified
13 foreign seller, the Secretary shall certify that
14 such seller—

15 “(i) is a foreign wholesale distributor
16 or licensed foreign pharmacy operating an
17 establishment, which may include an online
18 foreign pharmacy, that is located in Can-
19 ada, or, subject to subsection (e), another
20 permitted country;

21 “(ii) is engaged in the distribution or
22 dispensing of a prescription drug that is
23 imported or offered for importation into
24 the United States;

1 “(iii) has been in existence for a pe-
2 riod of at least 5 years preceding the date
3 of such certification and has a purpose
4 other than to participate in the program
5 established under this section;

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

12 “(v) has processes established by the
13 seller, or participates in another estab-
14 lished process, to certify that the physical
15 premises and data reporting procedures
16 and licenses are in compliance with all ap-
17 plicable laws and regulations of Canada,
18 or, subject to subsection (e), the permitted
19 country in which the seller is located, and
20 has implemented policies designed to mon-
21 itor ongoing compliance with such laws
22 and regulations;

23 “(vi) conducts or commits to partici-
24 pate in ongoing and comprehensive quality
25 assurance programs and implements such

1 quality assurance measures, including
2 blind testing, to ensure the veracity and re-
3 liability of the findings of the quality as-
4 surance program;

5 “(vii) agrees that, pursuant to sub-
6 section (g), laboratories approved by the
7 Secretary may be authorized to conduct
8 product testing to determine the chemical
9 authenticity of sample pharmaceutical
10 products;

11 “(viii) agrees to notify the Secretary,
12 importers, and individuals of product re-
13 calls in Canada, or pursuant to subsection
14 (e), the permitted country in which the
15 seller is located, and agrees to cease, or re-
16 frain from, exporting such product;

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

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

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

4 “(xi) meets any other criteria estab-
5 lished by the Secretary.

6 “(C) CERTIFICATION FEE.—Not later than
7 30 days before the start of each fiscal year, the
8 Secretary shall establish a fee to be collected
9 from foreign sellers for such fiscal year that are
10 certified under subparagraph (B), in an amount
11 that is sufficient, and not more than necessary,
12 to pay the costs of administering the program
13 under this section, and enforcing this section
14 pursuant to section 303(h), for that fiscal year.

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

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

1 section (b) from Canada or another country pursu-
2 ant to subsection (e) if such drug—

3 “(A) is dispensed, including through an
4 online pharmacy, by a certified foreign seller
5 that is a licensed foreign pharmacy;

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

9 “(C) is filled only after providing to the li-
10 censed foreign pharmacy a valid prescription
11 issued by a health care practitioner licensed to
12 practice in a State in the United States.

13 “(e) IMPORTATION FROM OTHER COUNTRIES.—Be-
14 ginning on the date that is 2 years after the date on which
15 final regulations are promulgated to carry out this section,
16 if, based on a review of the evidence obtained after such
17 effective date, including the reports submitted under sec-
18 tion 807(d) of the FDA Reauthorization Act of 2017, that
19 importation of qualifying prescription drugs from Canada
20 under this section resulted in cost savings for consumers
21 in the United States and increased access to safe medica-
22 tion, the Secretary shall have the authority to permit im-
23 portation of qualifying prescription drugs by importers
24 and individuals from, in addition to Canada, any country
25 that—

1 “(1) is a member of the Organisation for Eco-
2 nomic Co-operation and Development; and

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

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

13 “(B) requires that any determination of
14 safety and effectiveness described in subpara-
15 graph (A) be made on the basis of adequate
16 and well-controlled investigations, including
17 clinical investigations, as appropriate, con-
18 ducted by experts qualified by scientific training
19 and experience to evaluate the safety and effec-
20 tiveness of drugs;

21 “(C) requires the methods used in, and the
22 facilities and controls used for, the manufac-
23 ture, processing, and packing of drugs in the
24 country to be adequate to preserve the identity,
25 quality, purity, and strength of the drugs; and

1 “(D) requires the reporting of adverse re-
2 actions to drugs and establish procedures to re-
3 call, and withdraw approval of, drugs found not
4 to be safe or effective.

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

9 “(g) DRUG TESTING LABORATORIES.—The Sec-
10 retary may approve one or more laboratories to conduct
11 random testing of prescription drugs sold by certified for-
12 eign sellers to assess the chemical authenticity of such
13 drugs.

14 “(h) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
15 TICES.—It is unlawful for a manufacturer, directly or indi-
16 rectly (including by being a party to a licensing agreement
17 or other agreement)—

18 “(1) to discriminate by charging a higher price
19 for a prescription drug sold to a certified foreign
20 seller that sells such drug to an importer in accord-
21 ance with this section than the price that is charged,
22 inclusive of rebates or other incentives to the coun-
23 try from which the drug is exported, to another per-
24 son that is in the same country and that does not

1 import such a drug into the United States in accord-
2 ance with this section;

3 “(2) except with respect to a prescription drug
4 on the drug shortage list under section 506E, dis-
5 criminate by denying, restricting, or delaying sup-
6 plies of a prescription drug to a certified foreign sell-
7 er, on account of such seller’s status as a certified
8 foreign seller, that sells such drug to an importer in
9 accordance with this section, or by publicly, pri-
10 vately, or otherwise refusing to do business with
11 such a certified foreign seller on account of such
12 seller’s status as a certified foreign seller;

13 “(3) cause there to be a difference (including a
14 difference in active ingredient, route of administra-
15 tion, bioequivalence, strength, formulation, manufac-
16 turing establishment, manufacturing process, or per-
17 son that manufactures the drug) between a prescrip-
18 tion drug for distribution in the United States and
19 the drug for distribution in Canada or another per-
20 mitted country, subject to subsection (e), for the
21 purpose of avoiding sales by certified foreign sellers;
22 or

23 “(4) except with respect to a prescription drug
24 on the drug shortage list under section 506E, en-
25 gage in any other action to restrict, prohibit, or

1 delay the importation of a prescription drug under
2 this section.

3 “(i) INFORMATION AND RECORDS.—

4 “(1) BIENNIAL REPORTS.—Each importer shall
5 submit biennial reports to the Secretary which shall
6 contain, for each qualifying prescription drug im-
7 ported into the United States—

8 “(A) the unique facility identifier of the
9 manufacturer of the drug, described in section
10 510;

11 “(B) the transaction information described
12 in section 581(26) (other than the information
13 described in subparagraph (C)); and

14 “(C) the price paid by the importer for the
15 drug.

16 “(2) MAINTENANCE OF RECORDS BY SEC-
17 RETARY.—The Secretary shall maintain information
18 and documentation submitted under paragraph (1)
19 for such period of time as the Secretary determines
20 to be appropriate.

21 “(j) SUSPENSION OF IMPORTATION.—

22 “(1) PATTERNS OF NONCOMPLIANCE.—The
23 Secretary shall require that importation of a specific
24 qualifying prescription drug or importation by a spe-
25 cific certified foreign seller or importer pursuant to

1 this section be immediately suspended if the Sec-
2 retary determines that there is a pattern of importa-
3 tion of such specific drug or by such specific seller
4 or importer that involves counterfeit drugs, drugs
5 that have been recalled or withdrawn, or drugs in
6 violation of any requirement of this section, until an
7 investigation is completed and the Secretary deter-
8 mines that importation of such drug or by such sell-
9 er or importer does not endanger the public health.

10 “(2) TEMPORARY SUSPENSION.—The Secretary
11 may require that importation of a specific qualifying
12 prescription drug or importation by a specific cer-
13 tified foreign seller or importer pursuant to this sec-
14 tion be temporarily suspended if, with respect to
15 such drug, seller, or importer, there is a violation of
16 any requirement of this section or if the Secretary
17 determines that importation of such drug or by such
18 seller or importer might endanger the public health.
19 Such temporary suspension shall apply until the Sec-
20 retary completes an investigation and determines
21 that importation of such drug or by such seller or
22 importer does not endanger the public health.

23 “(k) SUPPLY CHAIN SECURITY.—

24 “(1) PURCHASE FROM REGISTERED FACILITIES
25 AND CERTIFIED FOREIGN SELLERS.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraph (B), certified foreign sellers who
3 sell qualifying prescription drugs for importa-
4 tion into the United States pursuant to this
5 section may purchase such drugs only from
6 manufacturers or entities registered under sec-
7 tion 510 or other certified foreign sellers.

8 “(B) EXCEPTION.—Certified foreign sellers
9 who sell qualifying prescription drugs for im-
10 portation into the United States pursuant to
11 this section may purchase such drugs from for-
12 eign sellers in Canada or another permitted
13 country, even if such foreign seller is not a
14 manufacturer registered under section 510 or a
15 certified foreign seller, if the Secretary enters
16 into a memorandum of understanding or coop-
17 erative agreement with Canada, or such other
18 permitted country, to ensure compliance, to the
19 extent appropriate and feasible, with subchapter
20 H of chapter V. The Secretary shall seek to
21 enter into such a memorandum of under-
22 standing or cooperative agreement with Canada
23 and each country from which importation is
24 permitted under subsection (e).

1 “(2) IMPORTATION TRACING.—Certified foreign
2 sellers shall provide importers with the unique facil-
3 ity identifier associated with the manufacturer reg-
4 istered under section 510 of the qualifying prescrip-
5 tion drug and the information under paragraph
6 (25), paragraph (26) (other than subparagraph (C)),
7 and subparagraphs (D), (F), and (G) of paragraph
8 (27) of section 581. Certified foreign sellers shall
9 provide such information to individuals purchasing
10 such drugs, upon request.

11 “(1) REMS.—In the case of an importer that imports
12 a qualifying prescription drug, where the drug with the
13 same active ingredient or ingredients (or that is biosimilar
14 to an approved biological product), route of administra-
15 tion, and strength that is approved under chapter V or
16 section 351 of the Public Health Service Act is subject
17 to elements to assure safe use under section 505–1, such
18 importer shall be subject to such elements to assure safe
19 use, as applicable and appropriate.

20 “(m) CONSTRUCTION.—Nothing in this section limits
21 the authority of the Secretary relating to the importation
22 of prescription drugs, other than with respect to section
23 801(d)(1) as provided in this section.”.

24 (b) PENALTIES WITH RESPECT TO ONLINE PHAR-
25 MACIES.—Section 303 of the Federal Food, Drug, and

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

3 “(h) In the case of person operating an Internet
4 website, whether in the United States or in another coun-
5 try, that violates section 301(aa) by—

6 “(1) selling, by means of the Internet, with the
7 intent to defraud or mislead or with reckless dis-
8 regard for safety of the public, an adulterated or
9 counterfeit drug to an individual in the United
10 States; or

11 “(2) dispenses, by means of the Internet, a
12 drug to an individual in the United States who the
13 person knows or has reasonable cause to believe,
14 does not possess a valid prescription for that drug,
15 such person shall be imprisoned for not more than
16 10 years or fined not more than \$250,000.”.

17 (c) NO PREEMPTION.—Nothing in this section, in-
18 cluding the amendments made by this section, shall be
19 construed to preempt, alter, displace, abridge, or supplant
20 any remedy available under any State or Federal law, in-
21 cluding common law, that provides a remedy for civil re-
22 lief.

23 (d) REPORTS.—

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

1 out section 804 of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 384), as amended by this sec-
3 tion, and every 2 years thereafter, the Secretary of
4 Health and Human Services, after consultation with
5 appropriate Federal agencies, shall submit to Con-
6 gress and make public a report on the importation
7 of drugs into the United States.

8 (2) GAO REPORT.—Not later than 18 months
9 after the date on which final regulations are promul-
10 gated to carry out section 804 of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 384), as amend-
12 ed by this section, the Comptroller General of the
13 United States shall submit to Congress a report con-
14 taining an analysis of the implementation of the
15 amendments made by this section, including a review
16 of drug safety and cost-savings and expenses, includ-
17 ing cost-savings to consumers in the United States
18 and trans-shipment and importation tracing proc-
19 esses, resulting from such implementation.