

Calendar No. 245

114TH CONGRESS
1ST SESSION

S. 481

To amend the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2015

Mr. HATCH (for himself, Mr. WHITEHOUSE, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

OCTOBER 1, 2015

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To amend the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Improving Regulatory
3 Transparency for New Medical Therapies Act”.

4 **SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW**
5 **FDA-APPROVED DRUGS.**

6 (a) **EFFECTIVE DATE OF APPROVAL.—**

7 (1) **EFFECTIVE DATE OF DRUG APPROVAL.—**

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

11 “(x) **DATE OF APPROVAL IN THE CASE OF REC-**
12 **OMMENDED CONTROLS UNDER THE CSA.—**

13 “(1) **IN GENERAL.—**In the case of an applica-
14 tion under subsection (b) with respect to a drug for
15 which the Secretary provides notice to the sponsor
16 that the Secretary intends to recommend controls
17 under the Controlled Substances Act, approval of
18 such application shall not take effect until the in-
19 terim final rule controlling the drug is issued in ac-
20 cordance with section 201(j) of the Controlled Sub-
21 stances Act.

22 “(2) **DATE OF APPROVAL.—**For purposes of
23 this section, with respect to an application described
24 in paragraph (1), the term ‘date of approval’ shall
25 mean the later of—

1 “(A) the date an application under sub-
2 section (b) is approved under subsection (e); or

3 “(B) the date of issuance of the interim
4 final rule controlling the drug.”.

5 (2) EFFECTIVE DATE OF APPROVAL OF BIO-
6 LOGICAL PRODUCTS.—Section 351 of the Public
7 Health Service Act (42 U.S.C. 262) is amended by
8 adding at the end the following:

9 “(n) DATE OF APPROVAL IN THE CASE OF REC-
10 OMMENDED CONTROLS UNDER THE CSA.—

11 “(1) IN GENERAL.—In the case of an applica-
12 tion under subsection (a) with respect to a biological
13 product for which the Secretary provides notice to
14 the sponsor that the Secretary intends to rec-
15 ommend controls under the Controlled Substances
16 Act, approval of such application shall not take ef-
17 fect until the interim final rule controlling the bio-
18 logical product is issued in accordance with section
19 201(j) of the Controlled Substances Act.

20 “(2) DATE OF APPROVAL.—For purposes of
21 this section, with respect to an application described
22 in paragraph (1), references to the date of approval
23 of such application, or licensure of the product sub-
24 ject to such application, shall mean the later of—

1 “(A) the date an application is approved
2 under subsection (a); or

3 “(B) the date of issuance of the interim
4 final rule controlling the biological product.”.

5 (3) EFFECTIVE DATE OF APPROVAL OF ANIMAL
6 DRUGS.—

7 (A) IN GENERAL.—Section 512 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C.
9 360b) is amended by adding at the end the fol-
10 lowing:

11 “(q) DATE OF APPROVAL IN THE CASE OF REC-
12 OMMENDED CONTROLS UNDER THE CSA.—

13 “(1) IN GENERAL.—In the case of an applica-
14 tion under subsection (b) with respect to a drug for
15 which the Secretary provides notice to the sponsor
16 that the Secretary intends to recommend controls
17 under the Controlled Substances Act, approval of
18 such application shall not take effect until the in-
19 terim final rule controlling the drug is issued in ac-
20 cordance with section 201(j) of the Controlled Sub-
21 stances Act.

22 “(2) DATE OF APPROVAL.—For purposes of
23 this section, with respect to an application described
24 in paragraph (1), the term ‘date of approval’ shall
25 mean the later of—

1 “(A) the date an application under sub-
2 section (b) is approved under subsection (e); or

3 “(B) the date of issuance of the interim
4 final rule controlling the drug.”.

5 (B) ~~CONDITIONAL APPROVAL.~~—Section
6 571(d) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 360ccc(d)) is amended by
8 adding at the end the following:

9 “(4)(A) In the case of an application under
10 subsection (a) with respect to a drug for which the
11 Secretary provides notice to the sponsor that the
12 Secretary intends to recommend controls under the
13 Controlled Substances Act, conditional approval of
14 such application shall not take effect until the in-
15 terim final rule controlling the drug is issued in ac-
16 cordance with section 201(j) of the Controlled Sub-
17 stances Act.

18 “(B) For purposes of this section, with respect
19 to an application described in subparagraph (A), the
20 term ‘date of approval’ shall mean the later of—

21 “(i) the date an application under sub-
22 section (a) is conditionally approved under sub-
23 section (b); or

24 “(ii) the date of issuance of the interim
25 final rule controlling the drug.”.

1 (C) INDEXING OF LEGALLY MARKETED
 2 UNAPPROVED NEW ANIMAL DRUGS.—Section
 3 572 of the Federal Food, Drug, and Cosmetic
 4 Act (21 U.S.C. 360ccc-1) is amended by add-
 5 ing at the end the following:

6 “(k) In the case of a request under subsection (d)
 7 to add a drug to the index under subsection (a) with re-
 8 spect to a drug for which the Secretary provides notice
 9 to the person filing the request that the Secretary intends
 10 to recommend controls under the Controlled Substances
 11 Act, a determination to grant the request to add such drug
 12 to the index shall not take effect, and the Secretary shall
 13 not list the drug on such index, until the interim final rule
 14 controlling the drug is issued in accordance with section
 15 201(j) of the Controlled Substances Act.”.

16 (4) DATE OF APPROVAL FOR DESIGNATED NEW
 17 ANIMAL DRUGS.—Section 573(e) of the Federal
 18 Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc-
 19 2(e)) is amended by adding at the end the following:

20 “(3) For purposes of determining the 7-year pe-
 21 riod of exclusivity under paragraph (1) for a drug
 22 for which the Secretary intends to recommend con-
 23 trols under the Controlled Substances Act, the drug
 24 shall not be considered approved or conditionally ap-
 25 proved until the date that the interim final rule con-

1 trolling the drug is issued in accordance with section
2 201(j) of the Controlled Substances Act.”.

3 (b) SCHEDULING OF NEWLY APPROVED DRUGS.—

4 Section 201 of the Controlled Substances Act (21 U.S.C.
5 811) is amended by inserting after subsection (i) the fol-
6 lowing:

7 “(j)(1) With respect to a drug referred to in sub-
8 section (f), if the Secretary of Health and Human Services
9 recommends that the Attorney General add the drug to
10 schedule II, III, IV, or V pursuant to subsections (a) and
11 (b), the Attorney General shall, not later than 90 days
12 after the date described in paragraph (2), issue an interim
13 final rule controlling the drug in accordance with such
14 subsections and section 202(b) using the procedures de-
15 scribed in paragraph (3).

16 “(2) The date described in this paragraph shall be
17 the later of—

18 “(A) the date on which the Attorney General
19 receives the scientific and medical evaluation and
20 recommendations from the Secretary of Health and
21 Human Services in accordance with subsection (b);
22 or

23 “(B) the date on which the Attorney General
24 receives notification from the Secretary of Health
25 and Human Services that the Secretary has ap-

1 proved an application under section 505(c), 512,
 2 571, or 572 of the Federal Food, Drug, and Cos-
 3 metic Act or section 351(a) of the Public Health
 4 Service Act with respect to the drug described in
 5 paragraph (1).

6 “(3) A rule issued by the Attorney General under
 7 paragraph (1) shall be in accordance with the procedures
 8 provided in subsection (a), except that the rule shall be-
 9 come immediately effective as an interim final rule without
 10 requiring the Attorney General to demonstrate good cause
 11 therefor. After publication of the interim final rule, the
 12 Attorney General shall issue a final rule in accordance
 13 with the procedures provided in subsection (a).”.

14 (c) EXTENSION OF PATENT TERM.—Section 156 of
 15 title 35, United States Code, is amended—

16 (1) in subsection (d)(1), in the matter pre-
 17 ceding subparagraph (A), by inserting “, or in the
 18 case of a drug product described in subsection (i)
 19 within the sixty-day period beginning on the covered
 20 date (as defined in subsection (i))” after “marketing
 21 or use”; and

22 (2) by adding at the end the following:

23 “(i)(1) For purposes of this section, if the Secretary
 24 of Health and Human Services provides notice to the
 25 sponsor of an application or request for approval, condi-

1 tional approval, or indexing of a drug product for which
 2 the Secretary intends to recommend controls under the
 3 Controlled Substances Act, beginning on the covered date,
 4 the drug product shall be considered to—

5 “(A) have been approved; and

6 “(B) have permission for commercial marketing
 7 or use.

8 “(2) In this subsection, the term ‘covered date’ means
 9 the later of—

10 “(A) the date an application is approved—

11 “(i) under section 351(a)(2)(C) of the
 12 Public Health Service Act; or

13 “(ii) under section 505(b) or 512(e) of the
 14 Federal Food, Drug, and Cosmetic Act;

15 “(B) the date an application is conditionally ap-
 16 proved under section 571(b) of the Federal Food,
 17 Drug, and Cosmetic Act;

18 “(C) the date a request for indexing is granted
 19 under section 572(d) of the Federal Food, Drug,
 20 and Cosmetic Act; or

21 “(D) the date of issuance of the interim final
 22 rule controlling the drug under section 201(j) of the
 23 Controlled Substances Act.”.

1 **SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.**

2 Section ~~303~~ of the Controlled Substances Act (~~21~~
3 U.S.C. ~~823~~) is amended by adding at the end the fol-
4 lowing:

5 “(i)(1) For purposes of registration to manufacture
6 a controlled substance under subsection (d) for use only
7 in a clinical trial, the Attorney General shall register the
8 applicant, or serve an order to show cause upon the appli-
9 cant in accordance with section ~~304(c)~~, not later than ~~180~~
10 days after the date on which the application is accepted
11 for filing.

12 “(2) For purposes of registration to manufacture a
13 controlled substance under subsection (a) for use only in
14 a clinical trial, the Attorney General shall, in accordance
15 with the regulations issued by the Attorney General, issue
16 a notice of application not later than 90 days after the
17 application is accepted for filing. Not later than 90 days
18 after the date on which the period for comment pursuant
19 to such notice ends, the Attorney General shall register
20 the applicant, or serve an order to show cause upon the
21 applicant in accordance with section ~~304(c)~~, unless the At-
22 torney General has granted a hearing on the application
23 under section ~~1008(i)~~ of the Controlled Substances Import
24 and Export Act.”.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Improving Regulatory*
 3 *Transparency for New Medical Therapies Act”.*

4 **SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW**
 5 **FDA-APPROVED DRUGS.**

6 (a) *EFFECTIVE DATE OF APPROVAL.—*

7 (1) *EFFECTIVE DATE OF DRUG APPROVAL.—Sec-*
 8 *tion 505 of the Federal Food, Drug, and Cosmetic Act*
 9 *(21 U.S.C. 355) is amended by adding at the end the*
 10 *following:*

11 “(x) *DATE OF APPROVAL IN THE CASE OF REC-*
 12 *OMMENDED CONTROLS UNDER THE CSA.—*

13 “(1) *IN GENERAL.—In the case of an application*
 14 *under subsection (b) with respect to a drug for which*
 15 *the Secretary provides notice to the sponsor that the*
 16 *Secretary intends to issue a scientific and medical*
 17 *evaluation and recommend controls under the Con-*
 18 *trolled Substances Act, approval of such application*
 19 *shall not take effect until the interim final rule con-*
 20 *trolling the drug is issued in accordance with section*
 21 *201(j) of the Controlled Substances Act.*

22 “(2) *DATE OF APPROVAL.—For purposes of this*
 23 *section, with respect to an application described in*
 24 *paragraph (1), the term ‘date of approval’ shall mean*
 25 *the later of—*

1 “(A) the date an application under sub-
2 section (b) is approved under subsection (c); or

3 “(B) the date of issuance of the interim
4 final rule controlling the drug.”.

5 (2) *EFFECTIVE DATE OF APPROVAL OF BIOLOGI-
6 CAL PRODUCTS.*—Section 351 of the Public Health
7 Service Act (42 U.S.C. 262) is amended by adding at
8 the end the following:

9 “(n) *DATE OF APPROVAL IN THE CASE OF REC-
10 OMMENDED CONTROLS UNDER THE CSA.*—

11 “(1) *IN GENERAL.*—In the case of an application
12 under subsection (a) with respect to a biological prod-
13 uct for which the Secretary provides notice to the
14 sponsor that the Secretary intends to issue a scientific
15 and medical evaluation and recommend controls
16 under the Controlled Substances Act, approval of such
17 application shall not take effect until the interim
18 final rule controlling the biological product is issued
19 in accordance with section 201(j) of the Controlled
20 Substances Act.

21 “(2) *DATE OF APPROVAL.*—For purposes of this
22 section, with respect to an application described in
23 paragraph (1), references to the date of approval of
24 such application, or licensure of the product subject to
25 such application, shall mean the later of—

1 “(A) the date an application is approved
2 under subsection (a); or

3 “(B) the date of issuance of the interim
4 final rule controlling the biological product.”.

5 (3) *EFFECTIVE DATE OF APPROVAL OF ANIMAL*
6 *DRUGS.*—

7 (A) *IN GENERAL.*—Section 512 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C.
9 360b) is amended by adding at the end the fol-
10 lowing:

11 “(q) *DATE OF APPROVAL IN THE CASE OF REC-*
12 *OMMENDED CONTROLS UNDER THE CSA.*—

13 “(1) *IN GENERAL.*—In the case of an application
14 under subsection (b) with respect to a drug for which
15 the Secretary provides notice to the sponsor that the
16 Secretary intends to issue a scientific and medical
17 evaluation and recommend controls under the Con-
18 trolled Substances Act, approval of such application
19 shall not take effect until the interim final rule con-
20 trolling the drug is issued in accordance with section
21 201(j) of the Controlled Substances Act.

22 “(2) *DATE OF APPROVAL.*—For purposes of this
23 section, with respect to an application described in
24 paragraph (1), the term ‘date of approval’ shall mean
25 the later of—

1 “(A) the date an application under sub-
2 section (b) is approved under subsection (c); or

3 “(B) the date of issuance of the interim
4 final rule controlling the drug.”.

5 (B) CONDITIONAL APPROVAL.—Section
6 571(d) of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 360ccc(d)) is amended by adding
8 at the end the following:

9 “(4)(A) In the case of an application under sub-
10 section (a) with respect to a drug for which the Sec-
11 retary provides notice to the sponsor that the Sec-
12 retary intends to issue a scientific and medical eval-
13 uation and recommend controls under the Controlled
14 Substances Act, conditional approval of such applica-
15 tion shall not take effect until the interim final rule
16 controlling the drug is issued in accordance with sec-
17 tion 201(j) of the Controlled Substances Act.

18 “(B) For purposes of this section, with respect to
19 an application described in subparagraph (A), the
20 term ‘date of approval’ shall mean the later of—

21 “(i) the date an application under sub-
22 section (a) is conditionally approved under sub-
23 section (b); or

24 “(ii) the date of issuance of the interim
25 final rule controlling the drug.”.

1 (C) INDEXING OF LEGALLY MARKETED UN-
 2 APPROVED NEW ANIMAL DRUGS.—Section 572 of
 3 the Federal Food, Drug, and Cosmetic Act (21
 4 U.S.C. 360ccc-1) is amended by adding at the
 5 end the following:

6 “(k) In the case of a request under subsection (d) to
 7 add a drug to the index under subsection (a) with respect
 8 to a drug for which the Secretary provides notice to the
 9 person filing the request that the Secretary intends to issue
 10 a scientific and medical evaluation and recommend controls
 11 under the Controlled Substances Act, a determination to
 12 grant the request to add such drug to the index shall not
 13 take effect until the interim final rule controlling the drug
 14 is issued in accordance with section 201(j) of the Controlled
 15 Substances Act.”.

16 (4) DATE OF APPROVAL FOR DESIGNATED NEW
 17 ANIMAL DRUGS.—Section 573(c) of the Federal Food,
 18 Drug, and Cosmetic Act (21 U.S.C. 360ccc-2(c)) is
 19 amended by adding at the end the following:

20 “(3) For purposes of determining the 7-year pe-
 21 riod of exclusivity under paragraph (1) for a drug for
 22 which the Secretary intends to issue a scientific and
 23 medical evaluation and recommend controls under the
 24 Controlled Substances Act, the drug shall not be con-
 25 sidered approved or conditionally approved until the

1 *date that the interim final rule controlling the drug*
 2 *is issued in accordance with section 201(j) of the Con-*
 3 *trolled Substances Act.”.*

4 *(b) SCHEDULING OF NEWLY APPROVED DRUGS.—Sec-*
 5 *tion 201 of the Controlled Substances Act (21 U.S.C. 811)*
 6 *is amended by inserting after subsection (i) the following:*
 7 *“(j)(1) With respect to a drug referred to in subsection*
 8 *(f), if the Secretary of Health and Human Services rec-*
 9 *ommends that the Attorney General control the drug in*
 10 *schedule II, III, IV, or V pursuant to subsections (a) and*
 11 *(b), the Attorney General shall, not later than 90 days after*
 12 *the date described in paragraph (2), issue an interim final*
 13 *rule controlling the drug in accordance with such sub-*
 14 *sections and section 202(b) using the procedures described*
 15 *in paragraph (3).*

16 *“(2) The date described in this paragraph shall be the*
 17 *later of—*

18 *“(A) the date on which the Attorney General re-*
 19 *ceives the scientific and medical evaluation and the*
 20 *scheduling recommendation from the Secretary of*
 21 *Health and Human Services in accordance with sub-*
 22 *section (b); or*

23 *“(B) the date on which the Attorney General re-*
 24 *ceives notification from the Secretary of Health and*
 25 *Human Services that the Secretary has approved an*

1 *application under section 505(c), 512, or 571 of the*
 2 *Federal Food, Drug, and Cosmetic Act or section*
 3 *351(a) of the Public Health Service Act, or indexed*
 4 *a drug under section 572 of the Federal Food, Drug,*
 5 *and Cosmetic Act, with respect to the drug described*
 6 *in paragraph (1).*

7 *“(3) A rule issued by the Attorney General under para-*
 8 *graph (1) shall become immediately effective as an interim*
 9 *final rule without requiring the Attorney General to dem-*
 10 *onstrate good cause therefor. The interim final rule shall*
 11 *give interested persons the opportunity to comment and to*
 12 *request a hearing. After the conclusion of such proceedings,*
 13 *the Attorney General shall issue a final rule in accordance*
 14 *with the scheduling criteria of subsections (b), (c), and (d)*
 15 *of this section and section 202(b).”.*

16 *(c) EXTENSION OF PATENT TERM.—Section 156 of*
 17 *title 35, United States Code, is amended—*

18 *(1) in subsection (d)(1), in the matter preceding*
 19 *subparagraph (A), by inserting “, or in the case of a*
 20 *drug product described in subsection (i), within the*
 21 *sixty-day period beginning on the covered date (as de-*
 22 *finied in subsection (i))” after “marketing or use”;*
 23 *and*

24 *(2) by adding at the end the following:*

1 “(i)(1) *For purposes of this section, if the Secretary*
 2 *of Health and Human Services provides notice to the spon-*
 3 *sor of an application or request for approval, conditional*
 4 *approval, or indexing of a drug product for which the Sec-*
 5 *retary intends to recommend controls under the Controlled*
 6 *Substances Act, beginning on the covered date, the drug*
 7 *product shall be considered to—*

8 “(A) *have been approved or indexed under the*
 9 *relevant provision of the Public Health Service Act or*
 10 *Federal Food, Drug, and Cosmetic Act; and*

11 “(B) *have permission for commercial marketing*
 12 *or use.*

13 “(2) *In this subsection, the term ‘covered date’ means*
 14 *the later of—*

15 “(A) *the date an application is approved—*

16 “(i) *under section 351(a)(2)(C) of the Pub-*
 17 *lic Health Service Act; or*

18 “(ii) *under section 505(b) or 512(c) of the*
 19 *Federal Food, Drug, and Cosmetic Act;*

20 “(B) *the date an application is conditionally ap-*
 21 *proved under section 571(b) of the Federal Food,*
 22 *Drug, and Cosmetic Act;*

23 “(C) *the date a request for indexing is granted*
 24 *under section 572(d) of the Federal Food, Drug, and*
 25 *Cosmetic Act; or*

1 “(D) the date of issuance of the interim final
 2 rule controlling the drug under section 201(j) of the
 3 Controlled Substances Act.”.

4 **SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.**

5 Section 303 of the Controlled Substances Act (21
 6 U.S.C. 823) is amended by adding at the end the following:

7 “(i)(1) For purposes of registration to manufacture a
 8 controlled substance under subsection (d) for use only in
 9 a clinical trial, the Attorney General shall register the ap-
 10 plicant, or serve an order to show cause upon the applicant
 11 in accordance with section 304(c), not later than 180 days
 12 after the date on which the application is accepted for fil-
 13 ing.

14 “(2) For purposes of registration to manufacture a
 15 controlled substance under subsection (a) for use only in
 16 a clinical trial, the Attorney General shall, in accordance
 17 with the regulations issued by the Attorney General, issue
 18 a notice of application not later than 90 days after the ap-
 19 plication is accepted for filing. Not later than 90 days after
 20 the date on which the period for comment pursuant to such
 21 notice ends, the Attorney General shall register the appli-
 22 cant, or serve an order to show cause upon the applicant
 23 in accordance with section 304(c), unless the Attorney Gen-
 24 eral has granted a hearing on the application under section

1 1008(i) of the Controlled Substances Import and Export
2 Act.”.

3 **SEC. 4. RE-EXPORTATION AMONG MEMBERS OF THE EURO-**
4 **PEAN ECONOMIC AREA.**

5 Section 1003 of the Controlled Substances Import and
6 Export Act (21 U.S.C. 953) is amended—

7 (1) in subsection(f)—

8 (A) in paragraph (5)—

9 (i) by striking “(5)” and inserting
10 “(5)(A)”;

11 (ii) by inserting “, except that the con-
12 trolled substance may be exported from a
13 second country that is a member of the Eu-
14 ropean Economic Area to another country
15 that is a member of the European Economic
16 Area, provided that the first country is also
17 a member of the European Economic Area”
18 before the period at the end; and

19 (iii) by adding at the end the fol-
20 lowing:

21 “(B) Subsequent to any re-exportation described
22 in subparagraph (A), a controlled substance may con-
23 tinue to be exported from any country that is a mem-
24 ber of the European Economic Area to any other such
25 country, if—

1 “(i) the conditions applicable with respect
 2 to the first country under paragraphs (1), (2),
 3 (3), (4), (6), and (7) are met by each subsequent
 4 country from which the controlled substance is
 5 exported pursuant to this paragraph; and

6 “(ii) the conditions applicable with respect
 7 to the second country under paragraphs (1), (2),
 8 (3), (4), (6), and (7) are met by each subsequent
 9 country to which the controlled substance is ex-
 10 ported pursuant to this paragraph.”; and

11 (B) in paragraph (6)—

12 (i) by striking “(6)” and inserting
 13 “(6)(A)”; and

14 (ii) by adding at the end the following:

15 “(B) In the case of re-exportation among mem-
 16 bers of the European Economic Area, within 30 days
 17 after each re-exportation, the person who exported the
 18 controlled substance from the United States delivers to
 19 the Attorney General—

20 “(i) documentation certifying that such re-
 21 exportation has occurred; and

22 “(ii) information concerning the consignee,
 23 country, and product.”; and

24 (2) by adding at the end the following:

1 “(g) *LIMITATION.*—Subject to paragraphs (5) and (6)
2 of subsection (f) in the case of any controlled substance in
3 schedule I or II or any narcotic drug in schedule III or
4 IV, the Attorney General shall not promulgate nor enforce
5 any regulation, subregulatory guidance, or enforcement pol-
6 icy which impedes re-exportation of any controlled sub-
7 stance among European Economic Area countries, includ-
8 ing by promulgating or enforcing any requirement that—

9 “(1) re-exportation from the first country to the
10 second country or re-exportation from the second
11 country to another country occur within a specified
12 period of time; or

13 “(2) information concerning the consignee, coun-
14 try, and product be provided prior to exportation of
15 the controlled substance from the United States or
16 prior to each re-exportation among members of the
17 European Economic Area.”.

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Reported with an amendment