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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Improving Regulatory Transparency for New Medical Therapies Act''.

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

(a) EFFECTIVE DATE OF APPROVAL.—

(1) EFFECTIVE DATE OF DRUG APPROVAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

''(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

''(A) the date an application under subsection (b) is approved under subsection (c); or

''(B) the date of issuance of the interim final rule controlling the drug.''.

(2) EFFECTIVE DATE OF APPROVAL OF BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(n) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

''(1) IN GENERAL.—In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act.

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

"(A) the date an application is approved under subsection (a); or

"(B) the date of issuance of the interim final rule controlling the biological product.".

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

(A) IN GENERAL.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

"(q) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

"(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

"(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

''(A) the date an application under subsection (b) is approved under subsection (c); or

''(B) the date of issuance of the interim final rule controlling the drug.''.

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

''(4)(A) In the case of an application under subsection (a) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, conditional approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(B) For purposes of this section, with respect to an application described in subparagraph (A), the term 'date of approval' shall mean the later of—

''(i) the date an application under subsection (a) is conditionally approved under subsection (b); or

''(ii) the date of issuance of the interim final rule controlling the drug.''.

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

"(k) In the case of a request under subsection (d) to add a drug to the index under subsection (a) with respect to a drug for which the Secretary provides notice to the person filing the request that the Secretary intends to recommend controls under the Controlled Substances Act, a determination to grant the request to add such drug to the index shall not take effect, and the Secretary shall not list the drug on such index, until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.".

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

"(3) For purposes of determining the 7-year period of exclusivity under paragraph (1) for a drug for which the Secretary intends to recommend controls under the Controlled Substances Act, the drug shall not be considered approved or conditionally approved until the date that the interim final rule con-

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

(b) SCHEDULING OF NEWLY APPROVED DRUGS.—Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by inserting after subsection (i) the following:

''(j)(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General add the drug to schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 202(b) using the procedures described in paragraph (3).

''(2) The date described in this paragraph shall be the later of—

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

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

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

''(3) A rule issued by the Attorney General under paragraph (1) shall be in accordance with the procedures provided in subsection (a), except that the rule shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. After publication of the interim final rule, the Attorney General shall issue a final rule in accordance with the procedures provided in subsection (a).''.

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

(1) in subsection (d)(1), in the matter preceding subparagraph (A), by inserting '', or in the case of a drug product described in subsection (i) within the sixty-day period beginning on the covered date (as defined in subsection (i))'' after ''marketing or use''; and

(2) by adding at the end the following:

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

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

"(A) have been approved; and

"(B) have permission for commercial marketing or use.

"(2) In this subsection, the term 'covered date' means the later of—

"(A) the date an application is approved—

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

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

"(B) the date an application is conditionally approved under section 571(b) of the Federal Food, Drug, and Cosmetic Act;

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

"(D) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act.".

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

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

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

''(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.''.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Improving Regulatory Transparency for New Medical Therapies Act".

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

(a) EFFECTIVE DATE OF APPROVAL.—

(1) EFFECTIVE DATE OF DRUG APPROVAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

"(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

"(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

"(A) the date an application under subsection (b) is approved under subsection (c); or

"(B) the date of issuance of the interim final rule controlling the drug.".

(2) EFFECTIVE DATE OF APPROVAL OF BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(n) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

"(1) IN GENERAL.—In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act.

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

"(A) the date an application is approved under subsection (a); or

"(B) the date of issuance of the interim final rule controlling the biological product.".

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

(A) IN GENERAL.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

"(q) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

"(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

"(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

"(A) the date an application under subsection (b) is approved under subsection (c); or

"(B) the date of issuance of the interim final rule controlling the drug.".

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

"(4)(A) In the case of an application under subsection (a) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, conditional approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

"(B) For purposes of this section, with respect to an application described in subparagraph (A), the term 'date of approval' shall mean the later of—

"(i) the date an application under subsection (a) is conditionally approved under subsection (b); or

"(ii) the date of issuance of the interim final rule controlling the drug.".

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

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

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

"(3) For purposes of determining the 7-year period of exclusivity under paragraph (1) for a drug for which the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, the drug shall not be considered approved or conditionally approved until the

date that the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.".

(b) SCHEDULING OF NEWLY APPROVED DRUGS.—Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by inserting after subsection (i) the following:

"(j)(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 202(b) using the procedures described in paragraph (3).

"(2) The date described in this paragraph shall be the later of—

"(A) the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary of Health and Human Services in accordance with subsection (b); or

"(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an

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

"(3) A rule issued by the Attorney General under paragraph (1) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 202(b).".

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

(1) in subsection (d)(1), in the matter preceding subparagraph (A), by inserting ", or in the case of a drug product described in subsection (i), within the sixty-day period beginning on the covered date (as defined in subsection (i))" after "marketing or use"; and

(2) by adding at the end the following:

"(i)(1) For purposes of this section, if the Secretary of Health and Human Services provides notice to the sponsor of an application or request for approval, conditional approval, or indexing of a drug product for which the Secretary intends to recommend controls under the Controlled Substances Act, beginning on the covered date, the drug product shall be considered to—

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

"(B) have permission for commercial marketing or use.

"(2) In this subsection, the term 'covered date' means the later of—

"(A) the date an application is approved—

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

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

"(B) the date an application is conditionally approved under section 571(b) of the Federal Food, Drug, and Cosmetic Act;

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

"(D) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act.".

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

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

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

"(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section

1008(i) of the Controlled Substances Import and Export Act.".

SEC. 4. RE-EXPORTATION AMONG MEMBERS OF THE EUROPEAN ECONOMIC AREA.

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

(1) in subsection(f)—

(A) in paragraph (5)—

(i) by striking "(5)" and inserting "(5)(A)";

(ii) by inserting ", except that the controlled substance may be exported from a second country that is a member of the European Economic Area to another country that is a member of the European Economic Area, provided that the first country is also a member of the European Economic Area" before the period at the end; and

(iii) by adding at the end the following:

"(B) Subsequent to any re-exportation described in subparagraph (A), a controlled substance may continue to be exported from any country that is a member of the European Economic Area to any other such country, if—

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

"(ii) the conditions applicable with respect to the second country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country to which the controlled substance is exported pursuant to this paragraph."; and

(B) in paragraph (6)—

(i) by striking "(6)" and inserting "(6)(A)"; and

(ii) by adding at the end the following:

"(B) In the case of re-exportation among members of the European Economic Area, within 30 days after each re-exportation, the person who exported the controlled substance from the United States delivers to the Attorney General—

"(i) documentation certifying that such re-exportation has occurred; and

"(ii) information concerning the consignee, country, and product."; and

(2) by adding at the end the following:

"(g) LIMITATION.—Subject to paragraphs (5) and (6) of subsection (f) in the case of any controlled substance in schedule I or II or any narcotic drug in schedule III or IV, the Attorney General shall not promulgate nor enforce any regulation, subregulatory guidance, or enforcement policy which impedes re-exportation of any controlled substance among European Economic Area countries, including by promulgating or enforcing any requirement that—

"(1) re-exportation from the first country to the second country or re-exportation from the second country to another country occur within a specified period of time; or

"(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States or prior to each re-exportation among members of the European Economic Area.".

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