Hatch

AMENDMENT NO. 2 Calendar No._____

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

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

S. 934

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. HATCH

Viz:

At the appropriate place, insert the following:

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

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

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

"(a) DESIGNATION.—

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

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

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

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

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

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

"(2) REVOCATION OF DESIGNATION.—

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

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

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

"(b) EXTENSION.—

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

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

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

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

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

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

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

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

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

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

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

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

(c) CONFORMING AMENDMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

(d) GAO REPORT.—

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

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

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

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

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

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

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

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

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

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

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

(2) in subsection (b)—

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

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

exclusive approval or licensure cannot ensure"; and

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

(3) by adding at the end the following:

"(c) CONDITION OF CLINICAL SUPERIORITY.—

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

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

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