''(4) The Secretary shall promptly notify a vaccine developer if—

''(A) the Secretary becomes aware of any change to information that was—

''(i) shared by the Secretary with the vaccine developer during a meeting under paragraph (2); or

''(ii) provided by the Secretary to the vaccine developer in one or more analyses under paragraph (3); and

''(B) the change to such information may have implications for the vaccine developer's vaccine research and development.''.

Subtitle I—Orphan Product Extensions Now; Incentives for Certain Products for Limited Populations

SEC. 2151. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 2063, is further amended by inserting after section 505F of such Act 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 for marketing 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 notice being given by

the Secretary under paragraph (4) respecting 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) NOTIFICATION PRIOR TO DISCONTINUANCE OF PRODUCTION FOR SOLELY COMMERCIAL REASONS.—A designation of a drug under paragraph (1) shall be subject to the condition that the sponsor of the drug will notify the Secretary of any discontinuance of the production of the drug for solely commercial reasons at least one year before such discontinuance.

''(4) NOTICE TO PUBLIC.—Notice respecting the designation of a drug under paragraph (1) shall be made available to the public.

''(b) EXTENSION.—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)—

''(1)(A) 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

''(B) 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

''(2)(A) 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

''(B) 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).

''(c) RELATION TO PEDIATRIC AND QUALIFIED INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any extension under subsection (b) 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.

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

''(e) 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)) on or after the date of the enactment of this Act.

(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 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.''.

(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.—Notwithstanding 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.''.

SEC. 2152. REAUTHORIZATION OF RARE PEDIATRIC DISEASE PRIORITY REVIEW VOUCHER INCENTIVE PROGRAM.

(a) IN GENERAL.—Section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—

(1) in subsection (a)—

(A) in paragraph (3), by amending subparagraph (A) to read as follows:

''(A) The disease is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age

groups often called neonates, infants, children, and adolescents.''; and

(B) in paragraph (4)(A)—

(i) in subparagraph (E), by striking ''and'' at the end;

(ii) in subparagraph (F), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(G) is for a drug or biological product for which a priority review voucher has not been issued under section 524 (relating to tropical disease products).''; and

(2) in subsection (b), by striking paragraph (5) and inserting the following:

''(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after December 31, 2018.''.

(b) GAO STUDY AND REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the effectiveness of awarding priority review vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) in providing incentives for the

development of drugs that treat or prevent rare pediatric diseases (as defined in subsection (a)(3) of such section) that would not otherwise have been developed. In conducting such study, the Comptroller General shall examine the following:

(A) The indications for which each drug for which a priority review voucher was awarded under such section 529 was approved under section 505 of such Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(B) Whether the priority review voucher impacted a sponsor's decision to invest in developing a drug to treat or prevent a rare pediatric disease.

(C) An analysis of the drugs that utilized such priority review vouchers, which shall include—

(i) the indications for which such drugs were approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) whether unmet medical needs were addressed through the approval of such drugs, including, for each such drug—

(I) if an alternative therapy was previously available to treat the indication; and

(II) the benefit or advantage the drug provided over another available therapy;

(iii) the number of patients potentially treated by such drugs;

(iv) the value of the priority review voucher if transferred; and

(v) the length of time between the date on which a priority review voucher was awarded and the date on which it was used.

(D) With respect to the priority review voucher program under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff)—

(i) the resources used by, and burden placed on, the Food and Drug Administration in implementing such program, including the effect of such program on the Food

and Drug Administration's review of drugs for which a priority review voucher was not awarded or used;

(ii) the impact of the program on the public health as a result of the expedited review of applications for drugs that treat or prevent non-serious indications that are generally used by the broader public; and

(iii) alternative approaches to improving such program so that the program is appropriately targeted toward providing incentives for the development of clinically important drugs that—

(I) prevent or treat rare pediatric diseases; and

(II) would likely not otherwise have been developed to prevent or treat such diseases.

(2) REPORT.—Not later than December 31, 2017, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report containing the results of the study of conducted under paragraph (1).