Bob Casey, Jr.

AMENDMENT NO. 1 Calendar No._____

Purpose: To promote the development of safe drugs for neonates.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

S. 2700

To update the authorizing provisions relating to the workforces of the National Institutes of Health and the Food and Drug Administration, 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. CASEY (for himself and Mr. CASSIDY)

Viz:

At the appropriate place, insert the following:

SEC. _____. PROMOTING THE DEVELOPMENT OF SAFE AND EFFECTIVE THERAPIES FOR NEONATES.

Subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is amended by inserting after section 529 the following:

"SEC. 530. EXCLUSIVITY TO ENCOURAGE DEVELOPMENT OF SAFE AND EFFECTIVE THERAPIES FOR NEONATES.

"(a) DEFINITIONS.—In this section:

"(1) NEONATAL DRUG.—The term 'neonatal drug' means a drug for the prevention or treatment of a disease or condition of a preterm or full-term neonate.

"(2) NEONATAL DRUG APPLICATION.—The term 'neonatal drug application' means a human drug application, as defined in section 735(1), that—

"(A) is for a drug or biological product—

"(i) that is for the prevention or treatment of a disease or condition listed on the Priority List of Critical Needs for Neonates described in subsection (c); and

"(ii) that contains no active ingredient (including any ester or salt of the active ingredient) that has been previously approved in any other application under section 505(b)(1), 505(b)(2), or 505(j) of this Act or section 351(a) or 351(k) of the Public Health Service Act;

"(B) is submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act;

"(C) the Secretary determines to be eligible for a neonatal drug exclusivity voucher, in accordance with subsection (b);

"(D) relies on clinical data derived from studies examining a neonatal population and dosages of the drug intended for that population; and

"(E) is approved after the date of the enactment of this section.

"(3) NEONATAL DRUG EXCLUSIVITY VOUCHER.—The term 'neonatal drug exclusivity voucher' means a voucher issued by the Secretary to the sponsor of a neonatal drug application that entitles the holder of such voucher to one year of transferable extension of all existing patents and marketing exclusivities, including any extensions, for a single human drug with respect to an application submitted under section 505(b)(1) or for a single human biologic product with respect to an application submitted under section 351(a) of the Public Health Service Act, including the 6-month period described in section 505A, the 4- and 5-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, the 7-year period described in section 527, the 5-year period described in section 505E, and the 12-year period described in section 351(k)(7).

"(b) NEONATAL DRUG EXCLUSIVITY VOUCHER.—

"(1) IN GENERAL.—The Secretary shall award a neonatal drug exclusivity voucher to the sponsor of a neonatal drug application upon approval by the Secretary of such neonatal drug application.

"(2) TRANSFERABILITY.—

"(A) IN GENERAL.—The sponsor of a neonatal drug application that receives a neonatal drug exclusivity voucher under this section may transfer (including by sale) the voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351 of the Public Health Service Act has been approved, will be submitted, or has been submitted.

"(B) NONTRANSFERABILITY.—A neonatal exclusivity voucher may not be transferred to, or used for, a drug with respect to which all patents and exclusivities have expired as of the date of the transfer.

"(C) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 calendar days after such transfer.

"(D) PROHIBITION ON ADDITIONAL FEES.—The Secretary shall not apply a fee for the exercise of a voucher under this section. The preceding sentence shall not affect the authority of the Secretary to apply fees with respect to a neonatal drug application that are otherwise applicable under law.

"(E) REVOCATION OF VOUCHER.—The Secretary may revoke any neonatal exclusivity voucher if the neonatal drug product for which such voucher was awarded is not marketed in the United States within the 365-day period beginning on the date of the approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act.

"(3) LIMITATIONS.—

"(A) NO AWARD FOR PRIOR APPROVED APPLICATION.—A sponsor of a neonatal drug may not receive a voucher under this section if the neonatal drug application was submitted to the

Secretary prior to the date of enactment of this section.

"(B) REQUIRED PEDIATRIC RESEARCH.—The Secretary shall limit grants of exclusivity under this section to drugs that are not required to complete neonatal studies under section 505B.

"(C) NO COMBINING VOUCHERS.—A sponsor may not use a neonatal exclusivity voucher on a product for which the sponsor also intends to use a voucher obtained or purchased pursuant to section 524 or section 529.

"(4) NOTIFICATION OF INTENT TO USE VOUCHER.—

"(A) NOTIFICATION BY SPONSOR.—The sponsor of a human drug application intending to use a voucher awarded or transferred under this section shall notify the Secretary not later than 15 months prior to loss of patent and exclusivities on the drug for which the voucher will be redeemed, in such form as the Secretary may require.

"(B) NOTIFICATION BY SECRETARY.—Within 30 calendar days of such notification to the Secretary, the Secretary shall notify the

sponsor of its eligibility to redeem a voucher for the intended drug.

"(c) PRIORITY LIST OF CRITICAL NEEDS FOR NEONATES.—

"(1) IN GENERAL.—The Secretary, in consultation with the Pediatric Advisory Committee, the National Institutes of Health, the International Neonatal Consortium sponsored by Critical Path Institute, and other stakeholders, shall, within one year of the date of enactment of this section—

"(A) develop and publish a list of critical research priorities related to specific diseases or conditions common to the neonatal population (referred to as the 'Priority List of Critical Needs for Neonates');

"(B) issue guidance specific to the neonatal drug exclusivity voucher program; and

"(C) perform other activities necessary to support neonatal drug applications.

"(2) PUBLIC COMMENT.—The Secretary shall provide a period of public notice and comment on the proposed list and shall hold public meetings to elicit input from patient advocacy and other organizations prior to publishing the final list.

"(3) SUBSEQUENT UPDATE.—The Secretary may revise, and publish in accordance with paragraph (1)(A), the Priority List of Critical Needs for Neonates every 3 years, or as frequently as the Secretary determines necessary.

"(4) RESTRICTION ON REMOVAL FROM LIST.—No disease or condition on the Priority List of Critical Needs for Neonates may be removed until after completion of the study and report under subsection (d).

"(d) GAO STUDY AND REPORT.—

"(1) STUDY.—

"(A) IN GENERAL.—Beginning 8 years after the date of enactment of this section or on the date that the Secretary awards the third neonatal exclusivity voucher under this section, whichever is earlier, the Comptroller General of the United States shall conduct a study of the effectiveness of the program under this section for the development of human drugs to treat and prevent diseases or conditions in the neonatal population.

"(B) CONTENTS OF THE STUDY.—In conducting the study under subparagraph (A), the

Comptroller General shall examine the following:

"(i) The number of neonatal drug vouchers awarded under this section.

"(ii) The indications for each drug for which a neonatal exclusivity voucher was approved under section 505 or section 351 of the Public Health Service Act, and whether any other drugs with indications for populations other than neonates were approved with an indication for neonates under those sections.

"(iii) Whether, and to what extent, an unmet need related to the treatment or prevention of a disease or condition that affects the neonatal population was met through the approval of a neonatal drug.

"(iv) The value of the neonatal exclusivity voucher if transferred.

"(v) Identification of each drug for which a neonatal exclusivity voucher was used.

"(vi) The length of the period of time between the date on which a neonatal ex-

clusivity voucher was awarded and the date on which it was used.

"(2) REPORT.—Not later than 1 year after the date under paragraph (1)(A), the Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study under paragraph (1).".