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To advance treatment and cures for blindness and other retinal conditions and to promote competitiveness in the United States through a pilot program to increase funding for translational research, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 18, 2018

Mr. SESSIONS (for himself, Mr. BISHOP of Georgia, Mr. UPTON, and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To advance treatment and cures for blindness and other retinal conditions and to promote competitiveness in the United States through a pilot program to increase funding for translational research, 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 ''Faster Treatments and Cures for Eye Diseases Act''.

SEC. 2. DEFINITIONS.

For purposes of this Act:

(1) APPLICABLE CONGRESSIONAL COMMITTEES.—The term ''applicable congressional committees'' means the Committees on Energy and Commerce and Financial Services of the House of Representatives and the Committees on Banking, Housing, and Urban Affairs and Health, Education, Labor, and Pensions of the Senate.

(2) APPROPRIATE FEDERAL BANKING AGENCY.—The term ''appropriate Federal banking agency'' has the meaning given that term in section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813).

(3) COST.—The term ''cost'' has the meaning given to the term ''cost of a loan guarantee'' in section 502(5)(C) of the Federal Credit Reform Act of 1990 (2 U.S.C. 661a(5)(C)).

(4) DEPOSITORY INSTITUTION; DEPOSITORY INSTITUTION HOLDING COMPANY.—The term ''depository institution'' and ''depository institution holding company'' have the meaning given those terms under section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813).

(5) EYE BOND.—The term ''eye bond'' means a bond—

(A) issued by an issuer pursuant to this Act;

(B) the proceeds of which are used to fund projects selected under section 6(b)(1), except as otherwise described in this Act; and

(C) that complies with the regulations issued under section 4.

(6) FUNDED PROJECT.—The term ''funded project'' means a translational research project that is selected to be funded using the proceeds of an eye bond.

(7) GUARANTEE.—The term ''guarantee'' has the meaning given to the term ''loan guarantee'' in section 502 of the Federal Credit Reform Act of 1990 (2 U.S.C. 661a) and includes a loan guarantee commitment (as defined in such section 502).

(8) ISSUER.—The term ''issuer'' means an entity that—

(A) is a depository institution, a depository institution holding company, or a broker or dealer registered with the Securities and Exchange Commission;

(B) complies with the schedule for the issuance of eye bonds established under section 3(c); and

(C) complies with the regulations issued under section 5.

(9) PROGRAM.—The term ''Program'' means the Eye Bond Pilot Program established under section 3.

(10) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services, except in references to the Secretary of the Treasury.

(11) STATE.—The term ''State'' means—

(A) each State of the United States;

(B) the District of Columbia;

(C) the Commonwealth of Puerto Rico; and

(D) any other territory or possession of the United States.

(12) TRANSLATIONAL RESEARCH.—The term ''translational research''—

(A) means any research project that is designed to cure vision blindness and any conditions attendant to vision impairment that are, as determined by the Director of the National Eye Institute, congenital to the vision impairment and not incidental to vision impairment or caused by vision impairment;

(B) includes projects designed to cure—

(i) hearing impairment genetically linked to vision impairment, such as Usher Syndrome;

(ii) retinal degenerative diseases such as retinitis pigmentosa, macular degeneration, and Usher Syndrome;

(iii) vision trauma due to injury such as that experienced by wounded veterans;

(iv) glaucoma;

(v) optic nerve disorders that result in vision impairment or blindness, such as morning glory syndrome; and

(vi) diabetic reinopathy; and

(C) subject to subparagraph (B)(vi), does not include projects designed to cure any underlying disease or condition whose symptoms may include vision impairment, such as diabetes.

SEC. 3. EYE BOND PILOT PROGRAM.

(a) ESTABLISHMENT.—Not earlier than 1 year after the date of enactment of this Act, the Secretary, in consultation with the Secretary of the Treasury and the appropriate Federal banking agencies, shall establish a pilot program to be known as the Eye Bond Pilot Program under which—

(1) the Director of the National Eye Institute shall, in accordance with section 6, select translational research projects to be funded by eye bonds; and

(2) the Secretary shall—

(A) provide a partial Federal guarantee of the eye bonds;

(B) contract with an issuer to issue the eye bonds; and

(C) use the proceeds from the sale of the eye bonds to fund the selected projects and to pay for other related expenses, as permitted by this Act.

(b) FEDERAL GUARANTEE.—

(1) IN GENERAL.—The Secretary shall guarantee the payment of principal (but not the payment of interest) on an eye bond, on a bond-by-bond basis, in an amount to be determined by the Secretary, but in no case may the amount of such guarantee be more than 50 percent of the principal of the eye bond.

(2) PRIORITIZATION OF TAXPAYER INTERESTS.—All eye bonds shall be structured to give first priority to protecting the interests of the United States by ensuring that—

(A) all cash proceeds received from the repayment of an eye bond are first used to reduce the amount of principal guaranteed by the Secretary under the terms of the eye bond; and

(B) the Secretary has a senior claim on all assets and collateral under the eye bond to the extent the guarantee provided by the Secretary is not extinguished.

(3) LIMITATION.—The Secretary may not guarantee—

(A) more than $1,000,000,000 for all eye bonds issued pursuant to this Act; and

(B) more than $250,000,000 for all eye bonds issued pursuant to this Act in any single fiscal year.

(c) ISSUANCE SCHEDULE.—The Secretary shall, in consultation with the Secretary of the Treasury and issuers, establish a schedule for the issuance of eye bonds that ensures that funded projects represent a reasonable sample of diverse causes of vision loss.

(d) RISK-SHARE POOL.—

(1) IN GENERAL.—With respect to an eye bond guaranteed under this section, the Secretary may allow a risk-share pool capitalized by issuers to provide a first-loss guarantee of the principal and inter-

est of such bond, if the Secretary determines that such first-loss guarantee would—

(A) be a robust source of protection for the United States, as guarantor of the eye bond, that reduces the cost of the Federal guarantee to the United States;

(B) encourage the flow of private sector capital into biomedical translational research;

(C) create a prudent incentive for issuers to contribute additional private capital for biomedical translational research; or

(D) meet other public interest, safety, and soundness goals.

(2) CONSULTATION.—In making a determination under paragraph (1), the Secretary shall consult with the Secretary of the Treasury and the appropriate Federal banking agencies.

(3) FUNDING.—The cost of contracting with a risk-share pool under this subsection shall be paid from the proceeds from the sale of eye bonds pursuant to the Program.

(e) EQUITY POSITION OPTION FOR THE SECRETARY.—

(1) IN GENERAL.—With respect to an eye bond issued pursuant to this Act, the Secretary, in con-

sultation with the Secretary of the Treasury and other appropriate parties, including eye bond issuers and investors, may negotiate an equity position for the United States Government in the projects to be funded by such eye bond if the Secretary determines that such an equity position will further the interests of the Program and the United States.

(2) LIMITATIONS.—

(A) SUPPLEMENTAL.—Any equity position taken in a project pursuant to paragraph (1) shall be supplemental to, not in lieu of, a guarantee provided by the Secretary with respect to the eye bond funding such project.

(B) TOTAL AMOUNT.—The total of amount of an eye bond guarantee under this section and any equity position taken by the Secretary in a project funded by such bond that is supplemental to such guarantee shall not exceed 50 percent of the principal amount of the eye bond.

(3) NOTIFICATION AND CONSULTATION.—Prior to finalization of any equity position under paragraph (1), the Secretary shall notify the applicable congressional committees and consult with such committees on the proposed terms of such equity po-

sition and whether taking such equity position will further the interests of the Program and the United States.

(f) TERMINATION OF THE PROGRAM.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Program shall terminate on the date that is 6 years after the date of enactment of this Act.

(2) EARLY TERMINATION.—

(A) IN GENERAL.—The Secretary may terminate the Program before the date described in paragraph (1).

(B) CONGRESSIONAL NOTIFICATION.—If the Secretary determines that the Program shall be terminated under subparagraph (A), not later than 60 days before the date on which the termination is effective, the Secretary shall—

(i) submit to the applicable congressional committees a report that includes—

(I) a description of the reasons for the termination;

(II) any corrective actions that may be taken; and

(III) any other actions that may be taken to promote the use of private capital and to increase the amount of Federal funds made available to carry out basic and translational biomedical research; and

(ii) make publicly available the report described in clause (i).

(3) EFFECT ON EYE BONDS ISSUED AND FEDERAL GUARANTEES.—The termination of the Program shall not affect the validity of—

(A) any eye bond issued before the date on which the Program is terminated; or

(B) any Federal guarantee under this Act for an eye bond described in subparagraph (A).

(g) PROGRAM FUNDING.—

(1) ADMINISTRATIVE EXPENSES PAID FROM BOND SALES.—Except as provided under paragraph (2), the cost of carrying out this Act, including the cost to the Secretary in administering the Program, shall be recovered from the proceeds from the sale of eye bonds pursuant to the Program or from fees as set forth in paragraph (3).

(2) SPECIFIC APPROPRIATION OR CONTRIBUTION.—No guarantee shall be made under this section unless—

(A) an appropriation for the full cost of the guarantee has been made;

(B) the Secretary has received from the eye bond issuer a payment in full for the cost of the guarantee; or

(C) a combination of an appropriation and the deposit of a payment from the bond issuer into the Treasury has been made in a sufficient amount to cover the full cost of the guarantee.

(3) COST OF GUARANTEES.—

(A) IN GENERAL.—The Secretary shall charge and collect fees for guarantees under this section in amounts the Secretary determines are sufficient to recover applicable administrative expenses.

(B) AVAILABILITY.—Fees collected under this subsection—

(i) shall be deposited by the Secretary into the Treasury; and

(ii) are authorized to remain available until expended.

SEC. 4. EYE BOND TERMS, CONDITIONS, AND STRUCTURE.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary, in consultation with the Secretary of the Treasury, the Chairman of the Securities and Exchange Commission, the heads of the appropriate Federal banking agencies, the Director of the National Institutes of Health, and the heads of other Federal departments and agencies and other interested parties as the Secretary determines appropriate, shall issue regulations to specify the terms, conditions, and structure for an eye bond.

(b) AUCTIONS.—In issuing the regulations under subsection (a)—

(1) the Secretary may provide for an auction to select the purchasers of eye bonds; and

(2) any such auction may include a process that minimizes the risk to the Government of the Federal guarantee involved by allowing bidders for an eye bond to compete against each other by bidding on the percentage of the Federal guarantee under section 4(b) with respect to the eye bond, with the bid for the lowest percentage winning the auction, taking into account other terms and conditions set by the issuer to ensure the lowest total cost to the Government.

SEC. 5. EYE BOND ISSUERS.

(a) ISSUER CRITERIA.—Not later than 180 days after the date of enactment of this Act, the Secretary, in consultation with the Secretary of the Treasury, shall issue regulations—

(1) to establish the criteria for selecting issuers;

(2) to ensure that issuers perform in a manner that ensures the successful issuance of eye bonds that promote biomedical translational research in the United States; and

(3) to ensure that issuers use sound underwriting practices that protect the interests of—

(A) the United States;

(B) eye bond investors; and

(C) the long-term promotion of translational research for vision impairment and other diseases, disabilities, and syndromes congenital to vision impairment or caused by vision impairment, taking into account features that are valuable after any authorization for expanded use of a limited Federal guarantee for biomedical translational research for other diseases and disabilities.

(b) COMPENSATION FOR ISSUERS.—The issuer of an eye bond shall be compensated from the proceeds from the

sale of such eye bond at such rate and on such terms as the Secretary may provide.

(c) PUBLIC DISCLOSURES WITH RESPECT TO EYE BONDS.—

(1) IN GENERAL.—Not less than 2 business days before the date on which an issuer issues an eye bond, the issuer shall file with the Securities and Exchange Commission, and make available to the public, the following information:

(A) The nature of all projects funded by the eye bond.

(B) The name of any principal individual or institution that will be conducting each project.

(C) The milestones established for each project.

(D) A determination by the issuer as to whether each project funded by the eye bond has appropriately protected intellectual property.

(E) The structure of the eye bond.

(F) The interest payment schedule for the eye bond.

(G) The anticipated returns and risks of the eye bond.

(H) Such other information as the Commission determines necessary or appropriate in the public interest or for the protection of investors.

(2) RULEMAKING.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Securities and Exchange Commission shall issue regulations to carry out this subsection.

(B) AUTHORITY OF THE SECRETARY.—If the Securities and Exchange Commission does not issue the regulations required under subparagraph (A) before the end of the 180-day period described under subparagraph (A), the Secretary shall issue regulations to carry out this subsection before the end of the 60-day period beginning on the end of the 180-day period described under subparagraph (A).

SEC. 6. TRANSLATIONAL RESEARCH PROJECTS.

(a) ELIGIBILITY REQUIREMENTS.—Not later than 180 days after the date of enactment of this Act, the Secretary, in consultation with the Secretary of the Treasury, the Director of the National Eye Institute, and other interested parties, shall issue final regulations for the eligibility criteria for selecting translational research projects

that will be funded through eye bonds. Such regulations shall address—

(1) the stage of clinical trial for projects to provide the greatest likelihood of commercial application;

(2) the variations among disease and conditions needed to ensure sufficient diversification in each eye bond; and

(3) the number of possible cures and treatments that are needed as determined by the Secretary, in consultation with issuers and the Director of the National Eye Institute, to ensure the successful issuance of eye bonds so as to protect the United States as guarantor of the eye bonds, including—

(A) drug therapies;

(B) gene therapies; and

(C) artificial restoration of sight and similar mechanisms.

(b) SELECTION OF PROJECTS.—

(1) IN GENERAL.—The Director of the National Eye Institute, in consultation with the Director of the National Institutes of Health and the Secretary of the Treasury, shall select translational research projects to be funded with the proceeds of an eye bond.

(2) FACTORS FOR SELECTION.—Not later than 30 days after the date on which the final regulations are issued under subsection (a), the Secretary shall submit to the Director of the National Eye Institute factors that the Director of the National Eye Institute shall consider in making the selection under paragraph (1), including—

(A) the amount of equity any intellectual property holder will hold in the project;

(B) the resources any individual or institution will be required to demonstrate to ensure the ability of the individual or institution to repay the obligation under the eye bond, regardless of the success or failure of the project funded with the proceeds of the eye bond;

(C) the number of projects needed to ensure diversification of risk;

(D) the manner in which funded projects will be defunded if the interim goals of the project are not satisfied; and

(E) such other factors related to biomedical translational research project selection as the Secretary determines appropriate.

(3) ADDITIONAL CONSULTATIONS.—

(A) IN GENERAL.—In carrying out paragraph (1), the Director of the National Eye Institute may establish any consultative body that the Director determines is necessary to provide for a complete, transparent, and forward-looking selection of projects.

(B) SCIENTIFIC ADVISERS.—In carrying out paragraph (1), the Director of the National Eye Institute may consult with any group of scientific advisers that the Director determines is necessary.

(c) ESTABLISHMENT OF MILESTONES.—

(1) IN GENERAL.—The Director of the National Eye Institute shall, for each project funded by an eye bond, establish milestones to determine the probability of success or failure for such project.

(2) INCLUSION IN FILINGS.—The Director of the National Eye Institute shall submit to the issuer of an eye bond the milestones for each project funded from such eye bond, so such milestones may be included in the filings made available by the issuer to the public under section 5(c).

(d) RESEARCH REQUIREMENT.—Translational research carried out under a project funded by an eye bond shall be conducted—

(1) in a State; and

(2) by an individual or institution that is—

(A) chartered in accordance with the laws of that State; and

(B) clearly subject to verification of beneficial ownership by the issuer and, upon request, by the Secretary.

SEC. 7. INAPPLICABILITY OF CERTAIN LAWS.

Eye bonds shall not be subject to—

(1) section 15G of the Securities Exchange Act of 1934 (15 U.S.C. 78o–11);

(2) except as provided under section 5(c), any registration or disclosure requirement promulgated by the Securities and Exchange Commission; and

(3) section 13 of the Bank Holding Company Act of 1956 (12 U.S.C. 1851).

SEC. 8. REPORTS.

(a) GAO STUDY AND REPORTS ON OTHER RESEARCH PROJECTS.—

(1) ONGOING STUDY.—The Comptroller General of the United States shall carry out an ongoing study to consider whether a program similar to the Eye Bond Pilot Program under this Act should be established for other biomedical research projects.

(2) REPORT.—The Comptroller General shall, during the period beginning on the date of the establishment of the Program and ending on the termination date of the Program, issue a report to the applicable congressional committees, not less frequently than annually, on all findings and determinations made in carrying out the study required under paragraph (1).

(b) REPORTS ON THE PROGRAM.—Not later than 2 years after the date on which eye bonds are first issued under this Act, and annually thereafter during the period ending on the date that is 4 years after the date on which eye bonds are first issued under this Act, the Comptroller General and the Director of the National Institutes of Health (in consultation with the Director of the National Center for Advancing Translational Sciences) shall each issue a separate report to the applicable congressional committees on—

(1) the progress of the issuance of eye bonds;

(2) the reasons for any problems achieving desired volumes of eye bonds or the ability of the Program to proceed at a faster pace;

(3) an analysis of the risk to the Government in providing the Federal guarantee described under section 4(b);

(4) any improvements to eye bonds that the Secretary should consider;

(5) the applicability of financial instruments similar to eye bonds to other biomedical research areas such as cancer, Alzheimer's disease, rare diseases or conditions (as defined in section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)) and syndromes of particular concern to children; and

(6) any other matter that the Comptroller General or the Director, respectively, determines is appropriate.

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