

115TH CONGRESS
2D SESSION

H. R. 6421

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Faster Treatments and
5 Cures for Eye Diseases Act”.

6 **SEC. 2. DEFINITIONS.**

7 For purposes of this Act:

1 (1) APPLICABLE CONGRESSIONAL COMMIT-
2 TEES.—The term “applicable congressional commit-
3 tees” means the Committees on Energy and Com-
4 merce and Financial Services of the House of Rep-
5 resentatives and the Committees on Banking, Hous-
6 ing, and Urban Affairs and Health, Education,
7 Labor, and Pensions of the Senate.

8 (2) APPROPRIATE FEDERAL BANKING AGEN-
9 CY.—The term “appropriate Federal banking agen-
10 cy” has the meaning given that term in section 3 of
11 the Federal Deposit Insurance Act (12 U.S.C.
12 1813).

13 (3) COST.—The term “cost” has the meaning
14 given to the term “cost of a loan guarantee” in sec-
15 tion 502(5)(C) of the Federal Credit Reform Act of
16 1990 (2 U.S.C. 661a(5)(C)).

17 (4) DEPOSITORY INSTITUTION; DEPOSITORY IN-
18 STITUTION HOLDING COMPANY.—The term “deposi-
19 tory institution” and “depository institution holding
20 company” have the meaning given those terms under
21 section 3 of the Federal Deposit Insurance Act (12
22 U.S.C. 1813).

23 (5) EYE BOND.—The term “eye bond” means a
24 bond—

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

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

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

8 (6) FUNDED PROJECT.—The term “funded
9 project” means a translational research project that
10 is selected to be funded using the proceeds of an eye
11 bond.

12 (7) GUARANTEE.—The term “guarantee” has
13 the meaning given to the term “loan guarantee” in
14 section 502 of the Federal Credit Reform Act of
15 1990 (2 U.S.C. 661a) and includes a loan guarantee
16 commitment (as defined in such section 502).

17 (8) ISSUER.—The term “issuer” means an enti-
18 ty that—

19 (A) is a depository institution, a depository
20 institution holding company, or a broker or
21 dealer registered with the Securities and Ex-
22 change Commission;

23 (B) complies with the schedule for the
24 issuance of eye bonds established under section
25 3(e); and

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

3 (9) PROGRAM.—The term “Program” means
4 the Eye Bond Pilot Program established under sec-
5 tion 3.

6 (10) SECRETARY.—The term “Secretary”
7 means the Secretary of Health and Human Services,
8 except in references to the Secretary of the Treas-
9 ury.

10 (11) STATE.—The term “State” means—

11 (A) each State of the United States;

12 (B) the District of Columbia;

13 (C) the Commonwealth of Puerto Rico;

14 and

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

17 (12) TRANSLATIONAL RESEARCH.—The term
18 “translational research”—

19 (A) means any research project that is de-
20 signed to cure vision blindness and any condi-
21 tions attendant to vision impairment that are,
22 as determined by the Director of the National
23 Eye Institute, congenital to the vision impair-
24 ment and not incidental to vision impairment or
25 caused by vision impairment;

- 1 (B) includes projects designed to cure—
- 2 (i) hearing impairment genetically
- 3 linked to vision impairment, such as Usher
- 4 Syndrome;
- 5 (ii) retinal degenerative diseases such
- 6 as retinitis pigmentosa, macular degenera-
- 7 tion, and Usher Syndrome;
- 8 (iii) vision trauma due to injury such
- 9 as that experienced by wounded veterans;
- 10 (iv) glaucoma;
- 11 (v) optic nerve disorders that result in
- 12 vision impairment or blindness, such as
- 13 morning glory syndrome; and
- 14 (vi) diabetic reinopathy; and
- 15 (C) subject to subparagraph (B)(vi), does
- 16 not include projects designed to cure any under-
- 17 lying disease or condition whose symptoms may
- 18 include vision impairment, such as diabetes.

19 **SEC. 3. EYE BOND PILOT PROGRAM.**

20 (a) ESTABLISHMENT.—Not earlier than 1 year after

21 the date of enactment of this Act, the Secretary, in con-

22 sultation with the Secretary of the Treasury and the ap-

23 propriate Federal banking agencies, shall establish a pilot

24 program to be known as the Eye Bond Pilot Program

25 under which—

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

5 (2) the Secretary shall—

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

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

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

14 (b) FEDERAL GUARANTEE.—

15 (1) IN GENERAL.—The Secretary shall guar-
16 antee the payment of principal (but not the payment
17 of interest) on an eye bond, on a bond-by-bond
18 basis, in an amount to be determined by the Sec-
19 retary, but in no case may the amount of such guar-
20 antee be more than 50 percent of the principal of
21 the eye bond.

22 (2) PRIORITIZATION OF TAXPAYER INTER-
23 ESTS.—All eye bonds shall be structured to give first
24 priority to protecting the interests of the United
25 States by ensuring that—

1 (A) all cash proceeds received from the re-
2 payment of an eye bond are first used to reduce
3 the amount of principal guaranteed by the Sec-
4 retary under the terms of the eye bond; and

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

9 (3) LIMITATION.—The Secretary may not guar-
10 antee—

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

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

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

21 (d) RISK-SHARE POOL.—

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

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

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

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

9 (C) create a prudent incentive for issuers
10 to contribute additional private capital for bio-
11 medical translational research; or

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

14 (2) CONSULTATION.—In making a determina-
15 tion under paragraph (1), the Secretary shall consult
16 with the Secretary of the Treasury and the appro-
17 priate Federal banking agencies.

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

22 (e) EQUITY POSITION OPTION FOR THE SEC-
23 RETARY.—

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

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

8 (2) LIMITATIONS.—

9 (A) SUPPLEMENTAL.—Any equity position
10 taken in a project pursuant to paragraph (1)
11 shall be supplemental to, not in lieu of, a guar-
12 antee provided by the Secretary with respect to
13 the eye bond funding such project.

14 (B) TOTAL AMOUNT.—The total of amount
15 of an eye bond guarantee under this section and
16 any equity position taken by the Secretary in a
17 project funded by such bond that is supple-
18 mental to such guarantee shall not exceed 50
19 percent of the principal amount of the eye
20 bond.

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

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

4 (f) TERMINATION OF THE PROGRAM.—

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

9 (2) EARLY TERMINATION.—

10 (A) IN GENERAL.—The Secretary may ter-
11 minate the Program before the date described
12 in paragraph (1).

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

19 (i) submit to the applicable congres-
20 sional committees a report that includes—

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

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

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

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

9 (3) EFFECT ON EYE BONDS ISSUED AND FED-
10 ERAL GUARANTEES.—The termination of the Pro-
11 gram shall not affect the validity of—

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

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

16 (g) PROGRAM FUNDING.—

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

1 (2) SPECIFIC APPROPRIATION OR CONTRIBU-
2 TION.—No guarantee shall be made under this sec-
3 tion unless—

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

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

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

13 (3) COST OF GUARANTEES.—

14 (A) IN GENERAL.—The Secretary shall
15 charge and collect fees for guarantees under
16 this section in amounts the Secretary deter-
17 mines are sufficient to recover applicable ad-
18 ministrative expenses.

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

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

23 (ii) are authorized to remain available
24 until expended.

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

2 (a) IN GENERAL.—Not later than 180 days after the
3 date of enactment of this Act, the Secretary, in consulta-
4 tion with the Secretary of the Treasury, the Chairman of
5 the Securities and Exchange Commission, the heads of the
6 appropriate Federal banking agencies, the Director of the
7 National Institutes of Health, and the heads of other Fed-
8 eral departments and agencies and other interested parties
9 as the Secretary determines appropriate, shall issue regu-
10 lations to specify the terms, conditions, and structure for
11 an eye bond.

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

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

16 (2) any such auction may include a process that
17 minimizes the risk to the Government of the Federal
18 guarantee involved by allowing bidders for an eye
19 bond to compete against each other by bidding on
20 the percentage of the Federal guarantee under sec-
21 tion 4(b) with respect to the eye bond, with the bid
22 for the lowest percentage winning the auction, tak-
23 ing into account other terms and conditions set by
24 the issuer to ensure the lowest total cost to the Gov-
25 ernment.

1 **SEC. 5. EYE BOND ISSUERS.**

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

6 (1) to establish the criteria for selecting issuers;

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

11 (3) to ensure that issuers use sound under-
12 writing practices that protect the interests of—

13 (A) the United States;

14 (B) eye bond investors; and

15 (C) the long-term promotion of translation-
16 al research for vision impairment and other dis-
17 eases, disabilities, and syndromes congenital to
18 vision impairment or caused by vision impair-
19 ment, taking into account features that are val-
20 uable after any authorization for expanded use
21 of a limited Federal guarantee for biomedical
22 translational research for other diseases and
23 disabilities.

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

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

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

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

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

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

15 (C) The milestones established for each
16 project.

17 (D) A determination by the issuer as to
18 whether each project funded by the eye bond
19 has appropriately protected intellectual prop-
20 erty.

21 (E) The structure of the eye bond.

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

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

1 (H) Such other information as the Com-
2 mission determines necessary or appropriate in
3 the public interest or for the protection of in-
4 vestors.

5 (2) RULEMAKING.—

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

10 (B) AUTHORITY OF THE SECRETARY.—If
11 the Securities and Exchange Commission does
12 not issue the regulations required under sub-
13 paragraph (A) before the end of the 180-day
14 period described under subparagraph (A), the
15 Secretary shall issue regulations to carry out
16 this subsection before the end of the 60-day pe-
17 riod beginning on the end of the 180-day period
18 described under subparagraph (A).

19 **SEC. 6. TRANSLATIONAL RESEARCH PROJECTS.**

20 (a) ELIGIBILITY REQUIREMENTS.—Not later than
21 180 days after the date of enactment of this Act, the Sec-
22 retary, in consultation with the Secretary of the Treasury,
23 the Director of the National Eye Institute, and other in-
24 terested parties, shall issue final regulations for the eligi-
25 bility criteria for selecting translational research projects

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

3 (1) the stage of clinical trial for projects to pro-
4 vide the greatest likelihood of commercial applica-
5 tion;

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

9 (3) the number of possible cures and treat-
10 ments that are needed as determined by the Sec-
11 retary, in consultation with issuers and the Director
12 of the National Eye Institute, to ensure the success-
13 ful issuance of eye bonds so as to protect the United
14 States as guarantor of the eye bonds, including—

15 (A) drug therapies;

16 (B) gene therapies; and

17 (C) artificial restoration of sight and simi-
18 lar mechanisms.

19 (b) SELECTION OF PROJECTS.—

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

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

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

10 (B) the resources any individual or institu-
11 tion will be required to demonstrate to ensure
12 the ability of the individual or institution to
13 repay the obligation under the eye bond, re-
14 gardless of the success or failure of the project
15 funded with the proceeds of the eye bond;

16 (C) the number of projects needed to en-
17 sure diversification of risk;

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

21 (E) such other factors related to bio-
22 medical translational research project selection
23 as the Secretary determines appropriate.

24 (3) ADDITIONAL CONSULTATIONS.—

1 (A) IN GENERAL.—In carrying out para-
2 graph (1), the Director of the National Eye In-
3 stitute may establish any consultative body that
4 the Director determines is necessary to provide
5 for a complete, transparent, and forward-look-
6 ing selection of projects.

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

12 (c) ESTABLISHMENT OF MILESTONES.—

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

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

23 (d) RESEARCH REQUIREMENT.—Translational re-
24 search carried out under a project funded by an eye bond
25 shall be conducted—

1 (1) in a State; and

2 (2) by an individual or institution that is—

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

5 (B) clearly subject to verification of bene-
6 ficial ownership by the issuer and, upon re-
7 quest, by the Secretary.

8 **SEC. 7. INAPPLICABILITY OF CERTAIN LAWS.**

9 Eye bonds shall not be subject to—

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

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

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

17 **SEC. 8. REPORTS.**

18 (a) GAO STUDY AND REPORTS ON OTHER RE-
19 SEARCH PROJECTS.—

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

1 (2) REPORT.—The Comptroller General shall,
2 during the period beginning on the date of the estab-
3 lishment of the Program and ending on the termi-
4 nation date of the Program, issue a report to the ap-
5 plicable congressional committees, not less frequently
6 than annually, on all findings and determinations
7 made in carrying out the study required under para-
8 graph (1).

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

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

20 (2) the reasons for any problems achieving de-
21 sired volumes of eye bonds or the ability of the Pro-
22 gram to proceed at a faster pace;

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

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

3 (5) the applicability of financial instruments
4 similar to eye bonds to other biomedical research
5 areas such as cancer, Alzheimer's disease, rare dis-
6 eases or conditions (as defined in section 526 of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 360bb)) and syndromes of particular concern to chil-
9 dren; and

10 (6) any other matter that the Comptroller Gen-
11 eral or the Director, respectively, determines is ap-
12 propriate.

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