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H. R. 3437

To require the Secretary of Health and Human Services to guarantee BioBonds in order to provide funding for loans to eligible biomedical companies and universities to carry out clinical trials approved by the Food and Drug Administration, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 20, 2021

Mr. RUSH (for himself, Mr. FITZPATRICK, Mr. BISHOP of Georgia, Mr. CARSON, Mr. COHEN, Mr. COOPER, Mr. DANNY K. DAVIS of Illinois, Mr. GRIJALVA, Mr. LEVIN of California, Mr. SCHNEIDER, Ms. SEWELL, and Mr. THOMPSON of Mississippi) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the Secretary of Health and Human Services to guarantee BioBonds in order to provide funding for loans to eligible biomedical companies and universities to carry out clinical trials approved by the Food and Drug Administration, 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 ''Long-term Opportunities for Advancing New Studies for Biomedical Research Act'' or the ''LOANS for Biomedical Research Act''.

SEC. 2. BIOBONDS PROGRAM.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of the Treasury, shall establish a program, to be known as the ''Biobonds Program'', to increase innovative biomedical research into therapies to address unmet medical needs, under which biomedical researchers seeking to conduct clinical trials with respect to a drug or device, but who cannot secure appropriate funding to conduct such trials (as determined by the Secretary of the Treasury), receive financial assistance through—

(1) the purchasing of loans by fiscal agents under section 3; and

(2) the sale and guarantee of Biobonds comprised of these loans under section 4.

(b) BIOMEDICAL RESEARCHERS ELIGIBLE FOR FINANCIAL ASSISTANCE.—

(1) IN GENERAL.—A person shall be eligible to receive a loan under the Biobonds Program if such person is conducting or seeking to conduct research with respect to a drug or device that is—

(A) intended for use to meet an unmet medical need (as determined by the Secretary of Health and Human Services); and

(B) under investigation in a controlled clinical trial under—

(i) an investigational drug application in effect under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)) (as applicable); or

(ii) an investigational device exemption in effect under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)).

(2) RULEMAKING.—The Secretary of Health and Human Services, in consultation with the Secretary of the Treasury, shall issue rules to carry out this subsection.

SEC. 3. PURCHASE OF LOANS BY FISCAL AGENTS.

(a) IN GENERAL.—Fiscal agents shall purchase loans—

(1) made to an eligible recipient for the purpose of conducting the applicable clinical trial; and

(2) with respect to which the fiscal agent determines that the borrower has the ability to repay the loan, based on collateral and financial capabilities

and not on the prospects for success of the clinical trial.

(b) PRIORITY FOR LOANS.—The Secretary of Health and Human Services shall issue rules to require fiscal agents, in purchasing loans under this section, to—

(1) purchase loans with respect to a diverse range of biomedical projects and not to favor one disease or disability, but with priority given to loans with potential to address unmet public health needs across the spectrum of diseases and disabilities;

(2) consider as an important criterion for purchasing loans with respect to clinical trials that they are being conducted by women researchers or researchers who are members of a racial and ethnic minority group or disabled; and

(3) prioritize purchasing loans with respect to clinical trials that include, where appropriate, representative levels of women, members of a racial and ethnic minority groups, disabled individuals, and other diverse participants, as specified in guidance issued under section 505(b) of the Federal Food, Drug, and Cosmetic Act.

(c) MAXIMUM LOAN AMOUNT.—A fiscal agent may not purchase loans in any one year with respect to a single recipient in an amount more than $25,000,000.

(d) LOAN TERMS AND CONDITIONS.—The Secretary of Health and Human Services, in consultation with the Secretary of the Treasury, shall issue rules to—

(1) establish criteria for the terms for loans that are eligible for purchase under this section;

(2) establish criteria for the interest rate for loans that are eligible for purchase under this section, which shall be based on applicable rates for obligations of the Department of the Treasury of comparable maturity plus a rate to be determined by the Secretary of the Treasury to reflect—

(A) prevailing market conditions;

(B) taxpayer protection; and

(C) the need to ensure ample funding for clinical trials described under section 2; and

(3) permit the use of warrants and similar instruments with respect to loans that are eligible for purchase under this section, where necessary to protect taxpayer interests.

SEC. 4. BIOBONDS.

(a) ISSUANCE.—The fiscal agents shall issue bonds, to be known as ''BioBonds'', collateralized by loans purchased under this Act, and sell the BioBonds to investors.

(b) BIOBOND GUARANTEE.—The Secretary of Health and Human Services shall provide a guarantee on

the payment of principal (but not the payment of interest) for each BioBond, 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 90 percent of the principal of the BioBond.

(c) SIZE OF ISSUANCES.—The Secretary of Health and Human Services, in consultation with the Secretary of the Treasury, shall establish the size of each BioBond issuance, to ensure market acceptance, portfolio diversification, and the protection of taxpayer interests.

(d) AUCTIONS.—The Secretary of Health and Human Services may—

(1) authorize fiscal agents to use an auction to select the purchasers of BioBonds; and

(2) require such auction to include a process that minimizes the risk to the Government of the Federal guarantee involved by allowing bidders for a BioBond to compete against each other by bidding on the percentage of the Federal guarantee under subsection (b) with respect to the BioBond, 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.

(e) PORTFOLIO DIVERSITY.—With respect to an issuance of BioBonds and the loans collateralizing such issuance, no more than 15 percent of the principal amount of such issuance may relate to a group of related diseases or disabilities (as defined by the Secretary of Health and Human Services).

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

(1) all cash proceeds received from the repayment of a BioBond are first used to reduce the amount of principal guaranteed by the Secretary of Health and Human Services; and

(2) the Secretary of Health and Human Services has a senior claim on all assets and collateral under a BioBond to the extent the guarantee provided by the Secretary is not extinguished.

SEC. 5. FISCAL AGENTS.

(a) IN GENERAL.—The Secretary of the Treasury shall contract with institutions to carry out the duties of fiscal agents under this Act, under such criteria as the Secretary of Health and Human Services, in consultation with the Secretary of the Treasury, determines appropriate.

(b) SOUND UNDERWRITING PRACTICES.—The Secretary of the Treasury shall issue rules to ensure that fiscal agents use sound underwriting practices that protect the interests of—

(1) the United States;

(2) BioBond investors; and

(3) the long-term promotion of innovative biomedical research into therapies to address unmet medical needs.

(c) COMPENSATION.—A fiscal agent shall be compensated for performing duties under this Act from the proceeds from the sale of Biobonds issued by the fiscal agent, at such rate and on such terms as the Secretary of the Treasury may provide.

(d) RULEMAKING.—Not later than 180 days after the date of enactment of this Act, the Secretary of the Treasury shall issue final rules to carry out this section.

SEC. 6. 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 BioBonds Program should be established for other biomedical research projects.

(2) REPORT.—The Comptroller General shall issue a report to the Congress, not less frequently than annually, on all findings and determinations made in carrying out the study required under paragraph (1).

(b) REPORTS ON THE BIOBONDS PROGRAM.—Not later than 2 years after the date on which BioBonds are first issued, and annually thereafter during the period ending on the date that is 4 years after the date on which BioBonds are first issued, the Comptroller General and the Secretary of Health and Human Services shall each issue a separate report to the Congress on—

(1) the progress of the issuance of BioBonds;

(2) the reasons for any problems achieving desired volumes of BioBonds 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 recommended improvements to the Program; and

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

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—There is authorized to be appropriated to the Secretary of Health and Human Services to pay for the cost of guaranteeing BioBonds under this Act $10,000,000,000 for each of fiscal years 2022, 2023, and 2024.

(b) 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 of Health and Human Services in administering the BioBond Program, shall be recovered from the proceeds from the sale of BioBonds or from fees as set forth in paragraph (3).

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

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

(B) the Secretary has received from the BioBond 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 of Health and Human Services shall charge and collect fees for guarantees under this Act 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. 8. DEFINITIONS.

In this Act:

(1) 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)).

(2) ELIGIBLE RECIPIENT.—The term ''eligible recipient'' means a person described under section 2(b).

(3) FISCAL AGENT.—The term ''fiscal agent'' means a person selected as a fiscal agent under section 5(a).

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