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118TH CONGRESS
2D SESSION

H. R. 7539

To require the Secretary of the Treasury 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

MARCH 5, 2024

Mr. FITZPATRICK (for himself and Mr. BISHOP of Georgia) 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 the Treasury 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 the Treasury, in consultation with the Secretary of Health and Human Services, 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, receive financial assistance through—

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

(2) the sale and guarantee of BioBonds collateralized by such 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 the Treasury, in consultation with the Secretary of Health and Human Services, 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 under section 2(b) for the purpose of conducting the applicable clinical trial described in that section; 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 PURCHASE OF LOANS.—The Secretary of the Treasury shall issue rules to require fiscal agents, in purchasing loans under this section, to purchase loans with respect to a diverse range of biomedical projects and not to favor one disease or disability, and to give priority to loans with potential to address unmet public health needs across the spectrum of diseases and disabilities;

(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.—

(1) IN GENERAL.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall issue rules—

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

(B) to 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—

(i) prevailing market conditions;

(ii) taxpayer protection; and

(iii) the need to ensure ample funding for clinical trials described in section 2;

(C) in accordance with paragraph (2), to establish an upfront fee of not greater than 1 percent of each loan principal amount at origination to cover administrative and financing costs associated with the loans eligible for purchase under this section; and

(D) to 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.

(2) FEES.—

(A) IN GENERAL.—Fees established under paragraph (1)(C) shall be financed by addition of the appropriate amount reflecting each upfront fee to the balance of each loan upon origination and shall be collected in concert with all loan payments collected by the fiscal agent.

(B) REQUIREMENT.—If a loan is repaid ahead of its stated maturity, becomes delinquent, or defaults, then the full unpaid balance of a fee established under paragraph (1)(C)

that remains at such time shall be added to the principal that must be fully satisfied.

SEC. 4. BIOBONDS.

(a) ISSUANCE.—Each fiscal agent that purchases a loan under section 3 shall issue bonds, to be known as ''BioBonds'', collateralized by such loans, and sell the BioBonds to investors.

(b) BIOBOND GUARANTEE.—The Secretary of the Treasury shall provide a guarantee of not greater than 90 percent of the payment of principal (but not the payment of interest) for a BioBond.

(c) AUCTIONS.—The Secretary of the Treasury 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 Federal 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 Federal Government.

(d) PORTFOLIO DIVERSITY.—With respect to an issuance of BioBonds and the loans collateralizing such issuance, not greater 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).

(e) PRIORITIZATION OF TAXPAYER INTERESTS.—All proceeds received from Biobond issuance shall be invested in obligations of the Federal Government in order to ensure a revenue stream in addition to loan repayment that protects taxpayers. 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 and income derived from loan-proceed reinvestment are first used to reduce the amount of principal guaranteed by the Secretary of the Treasury;

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

(3) to the extent that a Biobond is fully repaid without resort to the guarantee, all proceeds from

reinvested funds shall be the property of the United States.

(f) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit underwriters from varying terms and conditions consistent with the rules issued by the Secretary of the Treasury with respect to BioBonds.

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 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 the Treasury, in consultation with 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 BioBonds 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 BioBonds 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 the Treasury to pay for the cost of guaranteeing BioBonds under this Act $10,000,000,000 for each of fiscal years 2025, 2026, and 2027.

(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 the Treasury in admin-

istering 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 BioBond issuer has been made in a sufficient amount to cover the full cost of the guarantee.

(3) GUARANTEE FEES.—The Secretary of the Treasury shall charge and collect fees for guarantees under this Act in amounts the Secretary determines are sufficient to recover applicable administrative expenses, and such fees—

(A) shall be available to the Secretary, without further appropriation, to pay for the administrative expenses related to guarantees under this Act; and

(B) are authorized to remain available until expended.

SEC. 8. DEFINITIONS.

In this Act, the following definitions apply:

(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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