

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

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.

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 “Long-term Opportuni-
5 ties for Advancing New Studies for Biomedical Research
6 Act” or the “LOANS for Biomedical Research Act”.

1 **SEC. 2. BIOBONDS PROGRAM.**

2 (a) IN GENERAL.—Not later than 180 days after the
3 date of enactment of this Act, the Secretary of the Treas-
4 ury, in consultation with the Secretary of Health and
5 Human Services, shall establish a program, to be known
6 as the “BioBonds Program”, to increase innovative bio-
7 medical research into therapies to address unmet medical
8 needs, under which biomedical researchers seeking to con-
9 duct clinical trials with respect to a drug or device, but
10 who cannot secure appropriate funding to conduct such
11 trials, receive financial assistance through—

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

14 (2) the sale and guarantee of BioBonds
15 collateralized by such loans under section 4.

16 (b) BIOMEDICAL RESEARCHERS ELIGIBLE FOR FI-
17 NANCIAL ASSISTANCE.—

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

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

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

1 (i) an investigational drug application
2 in effect under section 505(i) of the Fed-
3 eral Food, Drug, and Cosmetic Act (21
4 U.S.C. 355(i)) or section 351(a)(3) of the
5 Public Health Service Act (42 U.S.C.
6 262(a)(3)) (as applicable); or

7 (ii) an investigational device exemp-
8 tion in effect under section 520(g) of the
9 Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 360j(g)).

11 (2) RULEMAKING.—The Secretary of the Treas-
12 ury, in consultation with the Secretary of Health
13 and Human Services, shall issue rules to carry out
14 this subsection.

15 **SEC. 3. PURCHASE OF LOANS BY FISCAL AGENTS.**

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

18 (1) made to an eligible recipient under section
19 2(b) for the purpose of conducting the applicable
20 clinical trial described in that section; and

21 (2) with respect to which the fiscal agent deter-
22 mines that the borrower has the ability to repay the
23 loan, based on collateral and financial capabilities
24 and not on the prospects for success of the clinical
25 trial.

1 (b) PRIORITY FOR PURCHASE OF LOANS.—The Sec-
2 retary of the Treasury shall issue rules to require fiscal
3 agents, in purchasing loans under this section, to purchase
4 loans with respect to a diverse range of biomedical projects
5 and not to favor one disease or disability, and to give pri-
6 ority to loans with potential to address unmet public
7 health needs across the spectrum of diseases and disabil-
8 ities;

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

12 (d) LOAN TERMS AND CONDITIONS.—

13 (1) IN GENERAL.—The Secretary of the Treas-
14 ury, in consultation with the Secretary of Health
15 and Human Services, shall issue rules—

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

19 (B) to establish criteria for the interest
20 rate for loans that are eligible for purchase
21 under this section, which shall be based on ap-
22 plicable rates for obligations of the Department
23 of the Treasury of comparable maturity plus a
24 rate to be determined by the Secretary of the
25 Treasury to reflect—

- 1 (i) prevailing market conditions;
2 (ii) taxpayer protection; and
3 (iii) the need to ensure ample funding
4 for clinical trials described in section 2;

5 (C) in accordance with paragraph (2), to
6 establish an upfront fee of not greater than 1
7 percent of each loan principal amount at origi-
8 nation to cover administrative and financing
9 costs associated with the loans eligible for pur-
10 chase under this section; and

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

15 (2) FEES.—

16 (A) IN GENERAL.—Fees established under
17 paragraph (1)(C) shall be financed by addition
18 of the appropriate amount reflecting each up-
19 front fee to the balance of each loan upon origi-
20 nation and shall be collected in concert with all
21 loan payments collected by the fiscal agent.

22 (B) REQUIREMENT.—If a loan is repaid
23 ahead of its stated maturity, becomes delin-
24 quent, or defaults, then the full unpaid balance
25 of a fee established under paragraph (1)(C)

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

3 **SEC. 4. BIOBONDS.**

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

8 (b) BIOBOND GUARANTEE.—The Secretary of the
9 Treasury shall provide a guarantee of not greater than
10 90 percent of the payment of principal (but not the pay-
11 ment of interest) for a BioBond.

12 (c) AUCTIONS.—The Secretary of the Treasury
13 may—

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

16 (2) require such auction to include a process
17 that minimizes the risk to the Federal Government
18 of the Federal guarantee involved by allowing bid-
19 ders for a BioBond to compete against each other by
20 bidding on the percentage of the Federal guarantee
21 under subsection (b) with respect to the BioBond,
22 with the bid for the lowest percentage winning the
23 auction, taking into account other terms and condi-
24 tions set by the issuer to ensure the lowest total cost
25 to the Federal Government.

1 (d) PORTFOLIO DIVERSITY.—With respect to an
2 issuance of BioBonds and the loans collateralizing such
3 issuance, not greater than 15 percent of the principal
4 amount of such issuance may relate to a group of related
5 diseases or disabilities (as defined by the Secretary of
6 Health and Human Services).

7 (e) PRIORITIZATION OF TAXPAYER INTERESTS.—All
8 proceeds received from Biobond issuance shall be invested
9 in obligations of the Federal Government in order to en-
10 sure a revenue stream in addition to loan repayment that
11 protects taxpayers. All BioBonds shall be structured to
12 give first priority to protecting the interests of the United
13 States by ensuring that—

14 (1) all cash proceeds received from the repay-
15 ment of a BioBond and income derived from loan-
16 proceed reinvestment are first used to reduce the
17 amount of principal guaranteed by the Secretary of
18 the Treasury;

19 (2) the Secretary of the Treasury has a senior
20 claim on all assets and collateral under a BioBond
21 to the extent the guarantee provided by the Sec-
22 retary is not extinguished; and

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

1 reinvested funds shall be the property of the United
2 States.

3 (f) **RULE OF CONSTRUCTION.**—Nothing in this sec-
4 tion may be construed to prohibit underwriters from vary-
5 ing terms and conditions consistent with the rules issued
6 by the Secretary of the Treasury with respect to
7 BioBonds.

8 **SEC. 5. FISCAL AGENTS.**

9 (a) **IN GENERAL.**—The Secretary of the Treasury
10 shall contract with institutions to carry out the duties of
11 fiscal agents under this Act, under such criteria as the
12 Secretary determines appropriate.

13 (b) **SOUND UNDERWRITING PRACTICES.**—The Sec-
14 retary of the Treasury shall issue rules to ensure that fis-
15 cal agents use sound underwriting practices that protect
16 the interests of—

17 (1) the United States;

18 (2) BioBond investors; and

19 (3) the long-term promotion of innovative bio-
20 medical research into therapies to address unmet
21 medical needs.

22 (c) **COMPENSATION.**—A fiscal agent shall be com-
23 pensated for performing duties under this Act from the
24 proceeds from the sale of Biobonds issued by the fiscal

1 agent, at such rate and on such terms as the Secretary
2 of the Treasury may provide.

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

6 **SEC. 6. REPORTS.**

7 (a) GAO STUDY AND REPORTS ON OTHER RE-
8 SEARCH PROJECTS.—

9 (1) ONGOING STUDY.—The Comptroller Gen-
10 eral of the United States shall carry out an ongoing
11 study to consider whether a program similar to the
12 BioBonds Program should be established for other
13 biomedical research projects.

14 (2) REPORT.—The Comptroller General shall
15 issue a report to the Congress, not less frequently
16 than annually, on all findings and determinations
17 made in carrying out the study required under para-
18 graph (1).

19 (b) REPORTS ON THE BIOBONDS PROGRAM.—Not
20 later than 2 years after the date on which BioBonds are
21 first issued, and annually thereafter during the period
22 ending on the date that is 4 years after the date on which
23 BioBonds are first issued, the Comptroller General and
24 the Secretary of the Treasury, in consultation with the

1 Secretary of Health and Human Services, shall each issue
2 a separate report to the Congress on—

3 (1) the progress of the issuance of BioBonds;

4 (2) the reasons for any problems achieving de-
5 sired volumes of BioBonds or the ability of the
6 BioBonds Program to proceed at a faster pace;

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

10 (4) any recommended improvements to the
11 BioBonds Program; and

12 (5) any other matter that the Comptroller Gen-
13 eral or the Secretary, respectively, determines is ap-
14 propriate.

15 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

16 (a) IN GENERAL.—There is authorized to be appro-
17 priated to the Secretary of the Treasury to pay for the
18 cost of guaranteeing BioBonds under this Act
19 \$10,000,000,000 for each of fiscal years 2025, 2026, and
20 2027.

21 (b) PROGRAM FUNDING.—

22 (1) ADMINISTRATIVE EXPENSES PAID FROM
23 BOND SALES.—Except as provided under paragraph

24 (2), the cost of carrying out this Act, including the
25 cost to the Secretary of the Treasury in admin-

1 istering the BioBond Program, shall be recovered
2 from the proceeds from the sale of BioBonds or
3 from fees as set forth in paragraph (3).

4 (2) SPECIFIC APPROPRIATION OR CONTRIBU-
5 TION.—No guarantee shall be made under this Act
6 unless—

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

9 (B) the Secretary has received from the
10 BioBond issuer a payment in full for the cost
11 of the guarantee; or

12 (C) a combination of an appropriation and
13 the deposit of a payment from the BioBond
14 issuer has been made in a sufficient amount to
15 cover the full cost of the guarantee.

16 (3) GUARANTEE FEES.—The Secretary of the
17 Treasury shall charge and collect fees for guarantees
18 under this Act in amounts the Secretary determines
19 are sufficient to recover applicable administrative ex-
20 penses, and such fees—

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

1 (B) are authorized to remain available
2 until expended.

3 **SEC. 8. DEFINITIONS.**

4 In this Act, the following definitions apply:

5 (1) **COST.**—The term “cost” has the meaning
6 given to the term “cost of a loan guarantee” in sec-
7 tion 502(5)(C) of the Federal Credit Reform Act of
8 1990 (2 U.S.C. 661a(5)(C)).

9 (2) **ELIGIBLE RECIPIENT.**—The term “eligible
10 recipient” means a person described under section
11 2(b).

12 (3) **FISCAL AGENT.**—The term “fiscal agent”
13 means a person selected as a fiscal agent under sec-
14 tion 5(a).

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