

.....  
(Original Signature of Member)

116TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To establish the RaD Investment Fund to encourage the development of high-risk, high-return therapies for rare diseases, and for other purposes.

\_\_\_\_\_  
IN THE HOUSE OF REPRESENTATIVES

Mr. VARGAS introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To establish the RaD Investment Fund to encourage the development of high-risk, high-return therapies for rare diseases, 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 “Rare Disease Fund  
5 Act of 2019” or the “RaD Fund Act of 2019”.

6       **SEC. 2. FINDINGS.**

7       The Congress finds the following:

1           (1) That biomedicine is far more advanced  
2 today than even a decade ago is indisputable, but  
3 breakthroughs require years of translational re-  
4 search at a cost of hundreds of millions of dollars  
5 per trial and have a substantial likelihood of failure.

6           (2) The drug development pipeline is laden with  
7 unfavorable probabilities. On average, for every  
8 5,000–10,000 compounds that enter the drug dis-  
9 covery pipeline, just 250 progress to preclinical de-  
10 velopment—and only one will become an approved  
11 drug.

12           (3) Biotech and life sciences traditional financ-  
13 ing vehicles of private and public equity are becom-  
14 ing less effective funding sources because the needs  
15 and expectations of limited partners and share-  
16 holders are not consistent with the increasing com-  
17 plexity, risk, and duration of biomedical innovation.

18           (4) Industry professionals frequently refer to  
19 the “Valley of Death”—a steadily widening funding  
20 and resource gap that currently exists between basic  
21 research and clinical development, effectively limiting  
22 the field of potential novel therapies, technologies,  
23 and treatments for patients.

24           (5) The life sciences industry needs novel ap-  
25 proaches to early-stage drug development that better

1 manage risk, lower capital cost, improve research ef-  
2 fectiveness, create diverse portfolios, leverage risk-  
3 tolerant capital, and access new capital sources.

4 (6) One solution is to implement a financial  
5 structure in which a large number of biomedical pro-  
6 grams are funded by a single entity to substantially  
7 diversify the portfolio and thereby reduce risk. The  
8 entity can use securitization to finance its activities  
9 by issuing debt, which opens up a much larger pool  
10 of capital for investment.

11 (7) This approach involves two components:

12 (A) Creating large diversified portfolios,  
13 called “megafunds”, consisting of biomedical  
14 products at various stages of development; and

15 (B) Structuring the financing for these  
16 portfolios as combinations of equity and  
17 securitized debt.

18 (8) This innovation makes the investment op-  
19 portunity much more attractive to a large pool of in-  
20 stitutional investors that have historically not par-  
21 ticipated in financing for early-stage therapeutic de-  
22 velopment.

23 (9) Diversification reduces risk, so that an enti-  
24 ty can issue debt and equity, rather than the equity-  
25 only investments typically made by venture capital.

1           (10) A series of peer-reviewed simulations con-  
2           ducted by researchers at MIT suggested that a mod-  
3           est megafund model could be successfully imple-  
4           mented for rare diseases (e.g., rare genetic dis-  
5           orders, pediatric cancers, and orphan diseases) with  
6           as few as ten to twenty compounds and only \$400  
7           million in capital.

8           (11) A rare disease therapeutics fund could  
9           serve as a viable pilot project, while minimizing gov-  
10          ernmental exposure.

11          (12) In addition to appealing to traditional  
12          biotech VC investors, megafund investments may be  
13          attractive to pension funds, insurance companies,  
14          and other large institutional investors, while also po-  
15          tentially lowering drug prices for patients and the  
16          healthcare system.

17          (13) The Food and Drug Administration  
18          (FDA) may grant the orphan designation for thera-  
19          pies being studied for a rare disease or condition af-  
20          fecting fewer than 200,000 people in the United  
21          States, which reduces costs and provides financial  
22          incentives to encourage development of such thera-  
23          pies for underserved patient populations.

24          **SEC. 3. RAD INVESTMENT FUND.**

25          (a) ESTABLISHMENT.—

1           (1) IN GENERAL.—The Securities and Ex-  
2           change Commission shall organize under the laws of  
3           a State a corporation to be known as the “RaD  
4           Fund” (hereinafter in this Act referred to as the  
5           “Investment Fund”).

6           (2) QUALIFIED PORTFOLIO MANAGER.—As soon  
7           as practicable after organization, the Investment  
8           Fund shall hire a qualified portfolio manager whose  
9           mandate will be to acquire and manage a portfolio  
10          of biomedical research assets on behalf of the Invest-  
11          ment Fund.

12          (b) PURPOSE.—The purpose of the Investment Fund  
13          shall be to leverage the capital markets by issuing bonds  
14          to large institutional investors, accepting equity invest-  
15          ments, and purchasing rights to, funding the development  
16          of, and, once developed, selling ownership interests in rare  
17          disease therapeutics.

18          (c) PRIVATIZATION OF THE INVESTMENT FUND.—

19                (1) IN GENERAL.—As soon as practicable after  
20                the establishment of the Investment Fund, but in no  
21                case later than 2 years after the date of enactment  
22                of this Act, the Commission shall issue equity stock  
23                in the Investment Fund to private investors.

24                (2) TERMINATION OF GOVERNMENT OWNER-  
25                SHIP.—Upon the issuance of the equity stock de-

1 scribed under paragraph (1), the Government shall  
2 no longer hold any ownership interest in the Invest-  
3 ment Fund.

4 (3) PROHIBITION ON DIVIDENDS.—The Invest-  
5 ment Fund may not pay dividends on the equity  
6 stock of the Investment Fund while there are any  
7 outstanding guaranteed bonds of the Investment  
8 Fund issued pursuant to subsection (e)(1)(A).

9 (d) SALE OF OWNERSHIP INTERESTS.—

10 (1) IN GENERAL.—The Investment Fund—

11 (A) may sell a rare disease therapy owned  
12 by the Investment Fund at any time; and

13 (B) shall sell any rare disease therapy  
14 owned by the Investment Fund prior to the  
15 commencement of a phase 3 study (as such  
16 term is defined in section 312.21(b) of title 21,  
17 Code of Federal Regulations (or any successor  
18 regulations)).

19 (2) SALE REQUIREMENTS.—In any sale of a  
20 rare disease therapy, the Investment Fund shall  
21 make such sale through an open and transparent  
22 arms-length process and on commercially reasonable  
23 terms, which may include lump sum, upfront pay-  
24 ments, milestone payments, royalty payments, or  
25 any combination thereof.

1 (e) FUNDING THROUGH BOND ISSUANCES.—

2 (1) IN GENERAL.—The Investment Fund shall  
3 issue one or more classes of bonds, with a maturity  
4 of no more than 12 years and carrying such interest  
5 as the Investment Fund determines appropriate:

6 (A) GUARANTEED BONDS.—The Invest-  
7 ment Fund shall issue a class of bonds, in an  
8 aggregate amount of not more than  
9 \$350,000,000, that is guaranteed by the United  
10 States.

11 (B) UNGUARANTEED BONDS.—The Invest-  
12 ment Fund may issue one or more classes of  
13 bonds that are backed by the Investment Fund,  
14 but are not guaranteed by the United States.

15 (2) DEBT-TO-EQUITY RATIO OF GUARANTEED  
16 BONDS.—The Investment Fund may not issue any  
17 guaranteed bond pursuant to paragraph (1)(A) if  
18 the issuance of such bond would cause the Invest-  
19 ment Fund to exceed a debt-to-equity ratio of 1 to  
20 1.

21 (3) GUARANTEE FEE.—The Investment Fund  
22 shall pay the Commission a guarantee fee, which  
23 shall be set by the Commission in an amount equal  
24 to the expected cost of guaranteeing bonds of the In-  
25 vestment Fund under paragraph (1)(A).

1 (f) TREATMENT UNDER THE SECURITIES LAWS.—

2 (1) SECURITIES NOT TREATED AS GOVERN-  
3 MENT SECURITIES.—For purposes only of the secu-  
4 rities laws, the securities of the Investment Fund  
5 shall be treated as securities that are neither issued  
6 nor guaranteed by the Government.

7 (2) ACCREDITED INVESTOR REQUIREMENT.—  
8 Securities issued under this Act may only be pur-  
9 chased by accredited investors.

10 (g) INVESTMENT FUND NOT GUARANTEED BY THE  
11 UNITED STATES.—Except as provided under subsection  
12 (e)(1)(A), the full faith and credit of the United States  
13 shall not be pledged to the Investment Fund or any secu-  
14 rity of the Investment Fund.

15 (h) DIVERSIFICATION REQUIREMENT.—The Invest-  
16 ment Fund shall, during the 3-year period beginning on  
17 the date that the Investment Fund first purchases rights  
18 to a rare disease therapeutic, purchase the rights to at  
19 least 15 rare disease therapeutics.

20 (i) CONGRESSIONAL REPORT.—The Investment  
21 Fund shall issue an annual report to the Committee on  
22 Financial Services of the House of Representatives and  
23 the Committee on Banking, Housing, and Urban Affairs  
24 of the Senate containing a description of the status of the  
25 Investment Fund and the assets held by the Investment

1 Fund, including asset make up, diversification, leverage  
2 ratio, outstanding bonds (guaranteed or otherwise), and  
3 capitalization.

4 (j) AUTHORIZATION OF APPROPRIATIONS.—

5 (1) IN GENERAL.—There is authorized to be  
6 appropriated to the Commission \$3,000,000 to es-  
7 tablish the Investment Fund and complete the pri-  
8 vatization of the Investment Fund.

9 (2) REPAYMENT OF APPROPRIATIONS.—Not  
10 later than the end of the 36-month period beginning  
11 on the date the Investment Fund is privatized pur-  
12 suant to subsection (c), the Investment Fund shall  
13 reimburse the Government for the amount of any  
14 appropriation made pursuant to paragraph (1), plus  
15 interest on such amount.

16 (k) SUNSET.—The Investment Fund shall terminate  
17 after the end of the 18-month period following the later  
18 of—

19 (1) the date on which the last bond issued  
20 under subsection (e) matures; and

21 (2) the date on which the Investment Fund re-  
22 ceives the final payment for the sale of all rare dis-  
23 ease therapeutics owned by the Investment Fund.

24 **SEC. 4. DEFINITIONS.**

25 For purposes of this Act:

1           (1) ACCREDITED INVESTOR.—The term “ac-  
2           credited investor” has the meaning given such term  
3           under section 2(a) of the Securities Act of 1933 (15  
4           U.S.C. 77b(a)).

5           (2) COMMISSION.—The term “Commission”  
6           means the Securities and Exchange Commission.

7           (3) INVESTMENT FUND.—The term “Invest-  
8           ment Fund” means the RaD Investment Fund es-  
9           tablished under section 3(a).

10          (4) RARE DISEASE THERAPEUTICS.—The term  
11          “rare disease therapeutics” means a compound, bio-  
12          logic, medical device, or companion diagnostic that  
13          has been designated as a therapy for a rare disease  
14          or condition pursuant to section 526 of the Federal  
15          Food, Drug, and Cosmetic Act (21 U.S.C. 360bb).

16          (5) SECURITIES LAWS.—The term “securities  
17          laws” has the meaning given that term under section  
18          3(a) of the Securities Exchange Act of 1934 (15  
19          U.S.C. 78c(a)).