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(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.

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 ''Rare Disease Fund Act of 2019'' or the ''RaD Fund Act of 2019''.

SEC. 2. FINDINGS.

The Congress finds the following:

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

(2) The drug development pipeline is laden with unfavorable probabilities. On average, for every 5,000–10,000 compounds that enter the drug discovery pipeline, just 250 progress to preclinical development—and only one will become an approved drug.

(3) Biotech and life sciences traditional financing vehicles of private and public equity are becoming less effective funding sources because the needs and expectations of limited partners and shareholders are not consistent with the increasing complexity, risk, and duration of biomedical innovation.

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

(5) The life sciences industry needs novel approaches to early-stage drug development that better

manage risk, lower capital cost, improve research effectiveness, create diverse portfolios, leverage risk-tolerant capital, and access new capital sources.

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

(7) This approach involves two components:

(A) Creating large diversified portfolios, called ''megafunds'', consisting of biomedical products at various stages of development; and

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

(8) This innovation makes the investment opportunity much more attractive to a large pool of institutional investors that have historically not participated in financing for early-stage therapeutic development.

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

(10) A series of peer-reviewed simulations conducted by researchers at MIT suggested that a modest megafund model could be successfully implemented for rare diseases (e.g., rare genetic disorders, pediatric cancers, and orphan diseases) with as few as ten to twenty compounds and only $400 million in capital.

(11) A rare disease therapeutics fund could serve as a viable pilot project, while minimizing governmental exposure.

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

(13) The Food and Drug Administration (FDA) may grant the orphan designation for therapies being studied for a rare disease or condition affecting fewer than 200,000 people in the United States, which reduces costs and provides financial incentives to encourage development of such therapies for underserved patient populations.

SEC. 3. RAD INVESTMENT FUND.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Securities and Exchange Commission shall organize under the laws of a State a corporation to be known as the ''RaD Fund'' (hereinafter in this Act referred to as the ''Investment Fund'').

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

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

(c) PRIVATIZATION OF THE INVESTMENT FUND.—

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

(2) TERMINATION OF GOVERNMENT OWNERSHIP.—Upon the issuance of the equity stock de-

scribed under paragraph (1), the Government shall no longer hold any ownership interest in the Investment Fund.

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

(d) SALE OF OWNERSHIP INTERESTS.—

(1) IN GENERAL.—The Investment Fund—

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

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

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

(e) FUNDING THROUGH BOND ISSUANCES.—

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

(A) GUARANTEED BONDS.—The Investment Fund shall issue a class of bonds, in an aggregate amount of not more than $350,000,000, that is guaranteed by the United States.

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

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

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

(f) TREATMENT UNDER THE SECURITIES LAWS.—

(1) SECURITIES NOT TREATED AS GOVERNMENT SECURITIES.—For purposes only of the securities laws, the securities of the Investment Fund shall be treated as securities that are neither issued nor guaranteed by the Government.

(2) ACCREDITED INVESTOR REQUIREMENT.—Securities issued under this Act may only be purchased by accredited investors.

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

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

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

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

(j) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated to the Commission $3,000,000 to establish the Investment Fund and complete the privatization of the Investment Fund.

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

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

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

(2) the date on which the Investment Fund receives the final payment for the sale of all rare disease therapeutics owned by the Investment Fund.

SEC. 4. DEFINITIONS.

For purposes of this Act:

(1) ACCREDITED INVESTOR.—The term ''accredited investor'' has the meaning given such term under section 2(a) of the Securities Act of 1933 (15 U.S.C. 77b(a)).

(2) COMMISSION.—The term ''Commission'' means the Securities and Exchange Commission.

(3) INVESTMENT FUND.—The term ''Investment Fund'' means the RaD Investment Fund established under section 3(a).

(4) RARE DISEASE THERAPEUTICS.—The term ''rare disease therapeutics'' means a compound, biologic, medical device, or companion diagnostic that has been designated as a therapy for a rare disease or condition pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb).

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