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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to establish a process for externally led, science-focused drug development meetings, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. MATSUI introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a process for externally led, science-focused drug development meetings, 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 “Scientific External
5 Process for Educated Review of Therapeutics Act of
6 2025” or the “Scientific EXPERT Act of 2025”.

1 **SEC. 2. SCIENCE-FOCUSED DRUG DEVELOPMENT MEET-**
2 **INGS.**

3 The Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 301 et seq.) is amended by inserting after section
5 770 (21 U.S.C. 379dd) the following:

6 **“SEC. 770A. SCIENCE-FOCUSED DRUG DEVELOPMENT**
7 **MEETINGS.**

8 “(a) IN GENERAL.—The Secretary shall develop and
9 implement a process for externally led, science-focused
10 drug development meetings to provide an opportunity for
11 medical experts, drug sponsors, scientific organizations,
12 and patient organizations to—

13 “(1) discuss science-related challenges impact-
14 ing the development of drugs for rare diseases and
15 conditions;

16 “(2) identify scientific approaches and opportu-
17 nities to facilitate the development, review, and ap-
18 proval of such drugs; and

19 “(3) align on novel approaches for the develop-
20 ment of drugs for particular diseases, including ap-
21 propriate clinical trial designs and metrics, manufac-
22 turing standards, patient populations, clinical
23 endpoints, the use of biomarkers as surrogate
24 endpoints, and natural history as a control, to ad-
25 vance treatment options to address unmet medical
26 needs.

1 “(b) ARRANGEMENT.—

2 “(1) QUALIFIED THIRD PARTY CONVENOR.—

3 The Secretary shall enter into an arrangement with
4 the Reagan-Udall Foundation for the Food and
5 Drug Administration (in this section referred to as
6 the ‘Foundation’) under which the Foundation
7 agrees to convene EL–SFDD meetings in accord-
8 ance with this section.

9 “(2) MINIMUM NUMBER OF MEETINGS.—The
10 Foundation shall convene no fewer than four EL–
11 SFDD meetings each year, with each such meeting
12 focused on addressing a different rare disease or
13 condition or a different group of rare diseases and
14 conditions.

15 “(3) STEERING COMMITTEE.—

16 “(A) IN GENERAL.—The Foundation shall
17 establish and maintain a permanent steering
18 committee, to be known as the Science-Focused
19 Drug Development Multistakeholder Steering
20 Committee, to advise the Foundation on imple-
21 mentation of this section, including by—

22 “(i) establishing a process by which
23 medical experts, drug sponsors, scientific
24 organizations, patient organizations, and

1 other entities can provide suggested meet-
2 ing topics to the Foundation;

3 “(ii) reviewing such suggested meeting
4 topics for EL–SFDD meetings; and

5 “(iii) based on the criteria under sub-
6 paragraph (B), recommending to the
7 Foundation topics for EL–SFDD meet-
8 ings.

9 “(B) CRITERIA FOR MEETINGS.—In for-
10 mulating recommendations under subparagraph
11 (A), the Foundation shall consider—

12 “(i) unmet therapeutic needs;

13 “(ii) the size of the patient population
14 of the rare disease or condition;

15 “(iii) whether there were or are mul-
16 tiple products in development to prevent or
17 treat the rare disease or condition involved;

18 “(iv) whether there is a need for in-
19 creased regulatory flexibility to facilitate
20 the development of products;

21 “(v) whether the disease or condition
22 involved would benefit from clarity and
23 alignment on drug development questions
24 (such as clinical trial design, natural his-
25 tory as a control, appropriate clinical

1 endpoints, biomarkers that may serve as
2 surrogate endpoints, and other approaches)
3 to expedite drug development for such dis-
4 ease or condition; and

5 “(vi) whether the discussions about
6 such rare disease or condition may have
7 broader impact on other rare diseases and
8 conditions.

9 “(C) MEMBERSHIP.—The members of the
10 Steering Committee shall be subject to all rel-
11 evant conflict of interest policies of the Founda-
12 tion and shall include—

13 “(i) representatives of the Center for
14 Drug Evaluation and Research, the Center
15 for Biologics Evaluation and Research, and
16 the Center for Devices and Radiological
17 Health;

18 “(ii) academic and medical experts;

19 “(iii) patient representatives;

20 “(iv) industry representatives engaged
21 in the development of drugs for rare dis-
22 eases and conditions.

23 “(4) PLANNING PROCESS.—In planning an EL-
24 SFDD meeting under this section, the Foundation,

1 in consultation with the stakeholders listed in para-
2 graph (5), shall develop—

3 “(A) a list of the specific objectives of the
4 meeting related to key drug development issues
5 for the rare disease or condition, or group of
6 rare diseases and conditions, with a goal of ex-
7 pediting drug development;

8 “(B) a proposed agenda for the meeting;
9 and

10 “(C) a list of medical experts, drug spon-
11 sors, scientific organizations, patient organiza-
12 tions, and other entities to be invited to partici-
13 pate in the meeting.

14 “(5) AGENCY AND STAKEHOLDER ENGAGE-
15 MENT.—Throughout the process of planning an EL-
16 SFDD meeting, the Foundation shall consult with—

17 “(A) appropriate staff of the Food and
18 Drug Administration;

19 “(B) the Steering Committee established
20 under this subsection;

21 “(C) industry representatives engaged in
22 the development of products for rare diseases
23 and conditions to be discussed at such EL-
24 SFDD meeting;

1 “(D) patient representatives of rare dis-
2 eases and conditions under discussion in such
3 EL–SFDD meeting; and

4 “(E) other appropriate stakeholders.

5 “(6) POST-MEETING REPORTS.—

6 “(A) IN GENERAL.—Within 180 days after
7 an EL–SFDD meeting, the Foundation shall
8 make publicly available on the website of the
9 Food and Drug Administration—

10 “(i) a transcript and recording of the
11 meeting; and

12 “(ii) in consultation with the stake-
13 holders listed in paragraph (5), a summary
14 analysis of the input received during the
15 meeting that is relevant to approval or li-
16 censing of drugs for the rare disease or
17 condition involved.

18 “(B) CONTENTS.—Each publication under
19 subparagraph (A) shall include a clear identi-
20 fication of—

21 “(i) areas of consensus;

22 “(ii) areas where additional clarifica-
23 tion or information is needed to reach con-
24 sensus; and

1 “(iii) next steps agreed upon with the
2 Food and Drug Administration.

3 “(c) REPRESENTATIVES OF FDA REVIEW DIVI-
4 SIONS.—The Secretary shall require appropriate rep-
5 resentatives of the review divisions of the Food and Drug
6 Administration to participate in each EL–SFDD meeting
7 under this section.

8 “(d) RULES OF CONSTRUCTION.—Nothing in this
9 section shall be construed—

10 “(1) to prevent other third-party organizations
11 from organizing similarly structured EL–SFDD-like
12 meetings to discuss challenges in rare disease drug
13 development;

14 “(2) to require the Food and Drug Administra-
15 tion to participate in additional meetings described
16 in paragraph (1);

17 “(3) to alter the protections offered by laws,
18 regulations, or policies governing disclosure of con-
19 fidential commercial or trade secret information and
20 any other information exempt from disclosure pursu-
21 ant to section 552(b) of title 5, United States Code;

22 “(4) to limit the ability of the Secretary to con-
23 sult with individuals and organizations;

1 “(5) to create a legal right for consultation on
2 any matter or require the Secretary to meet with
3 any particular expert or stakeholder;

4 “(6) to alter agreed-upon goals and procedures
5 identified in the letters described in section 1001(b)
6 of the FDA User Fee Reauthorization Act of 2022;
7 or

8 “(7) to increase the number of review cycles for
9 drugs.

10 “(e) DEFINITIONS.—In this section:

11 “(1) The term ‘EL–SFDD meeting’ means an
12 externally led, science-focused drug development
13 meeting.

14 “(2) The terms ‘rare diseases and conditions’
15 and ‘rare disease or condition’ refer to a rare disease
16 or condition as that term is defined in section 526.

17 “(3) The term ‘Steering Committee’ means the
18 Science-Focused Drug Development Multistake-
19 holder Steering Committee established under sub-
20 section (b)(3).

21 “(f) AUTHORIZATION OF APPROPRIATIONS.—

22 “(1) IN GENERAL.—To carry out this section,
23 there is authorized to be appropriated \$1,000,000
24 for each of fiscal years 2026 through 2030.

1 “(2) RULE OF CONSTRUCTION.—Nothing in
2 this section shall be construed to prohibit the Foun-
3 dation from soliciting or accepting funds pursuant to
4 section 770(i) for the purposes of planning or oper-
5 ating an EL–SFDD meeting authorized by this sec-
6 tion.

7 **“SEC. 770B. REQUIRED ACTIONS FOLLOWING EL–SFDD**
8 **MEETINGS.**

9 “(a) INCORPORATION OF INPUT INTO RISK-BENEFIT
10 ASSESSMENTS.—In approving or licensing a drug under
11 subsection (c) or (j) of section 505 of this Act or sub-
12 section (a) or (k) of section 351 of the Public Health Serv-
13 ice Act, the Secretary shall make public a brief state-
14 ment—

15 “(1) stating whether any EL–SFDD meeting
16 under section 770A was held that was relevant to
17 such approval or licensure; and

18 “(2) if so, including a description of how the
19 Secretary incorporated input from such meeting in
20 the risk-benefit assessment described in section
21 505(d).

22 “(b) ANNUAL REPORT.—On an annual basis, the
23 Secretary shall submit a report to the Congress summa-
24 rizing—

1 “(1) the number and topics of EL–SFDD
2 meetings held during the reporting period;

3 “(2) the extent of participation in such meet-
4 ings from the review divisions of the Food and Drug
5 Administration;

6 “(3) the impact of EL–SFDD meetings on the
7 workload and resources of the Food and Drug Ad-
8 ministration; and

9 “(4) an assessment of how the input received
10 during such meetings was used in—

11 “(A) deliberations throughout the drug de-
12 velopment lifecycle;

13 “(B) regulatory decisionmaking; and

14 “(C) formulating recommendations for fu-
15 ture meetings.

16 “(c) DEFINITION.—In this section, the term ‘EL–
17 SFDD meeting’ has the meaning given to that term in
18 section 770A.

19 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
20 carry out this section, there is authorized to be appro-
21 priated \$1,000,000 for each of fiscal years 2026 through
22 2030.”.