

119TH CONGRESS
1ST SESSION

S. 822

To amend the Federal Food, Drug, and Cosmetic Act to establish a process for science-focused drug development meetings led by the Reagan-Udall Foundation for the Food and Drug Administration with respect to drugs for rare diseases and conditions, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2025

Ms. KLOBUCHAR (for herself and Mr. WICKER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a process for science-focused drug development meetings led by the Reagan-Udall Foundation for the Food and Drug Administration with respect to drugs for rare diseases and conditions, 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 Foundation led, science-focused
10 drug development meetings to provide an opportunity for
11 academic researchers and medical experts, drug sponsors,
12 scientific organizations, 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 Foundation under which the Foundation agrees
5 to convene EL–SFDD meetings regarding drugs for
6 rare diseases or conditions in accordance with this
7 section.

8 “(2) MINIMUM NUMBER OF MEETINGS.—The
9 Foundation shall convene no fewer than 4 EL–
10 SFDD meetings each year, with each such meeting
11 focused on addressing a different rare disease or
12 condition or a different group of rare diseases and
13 conditions.

14 “(3) STEERING COMMITTEE.—

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

21 “(i) establishing a process by which li-
22 censed and board-certified medical clini-
23 cians and academics with expertise in a
24 rare disease or condition, sponsors of
25 drugs for a rare disease or condition, sci-

entific organizations, rare disease or condition patient organizations, and other entities can provide suggested meeting topics to the Foundation;

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

“(iii) based on the criteria under subparagraph (B), recommending to the Foundation topics for EL–SFDD meetings.

“(B) CRITERIA FOR MEETINGS.—In formulating recommendations under subparagraph (A), the Foundation shall consider—

“(i) unmet therapeutic needs;

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

“(iii) whether there were or are multiple products in development to prevent or treat the rare disease or condition involved;

“(iv) whether there is a need for increased regulatory flexibility to facilitate the development of products;

“(v) whether the rare disease or condition involved would benefit from clarity and alignment on drug development ques-

1 tions (such as clinical trial design, natural
2 history as a control, appropriate clinical
3 endpoints, biomarkers that may serve as
4 surrogate endpoints, and other approaches)
5 to expedite drug development for such dis-
6 ease or condition; and

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

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

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

20 “(ii) academic and licensed and board-
21 certified medical clinicians;

22 “(iii) patient representatives; and

23 “(iv) industry representatives engaged
24 in the development of drugs for rare dis-
25 eases and conditions.

1 “(4) PLANNING PROCESS.—In planning an EL-
 2 SFDD meeting under this section, the Foundation,
 3 in consultation with the stakeholders listed in para-
 4 graph (5), shall develop—

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

10 “(B) a proposed agenda for the meeting;
 11 and

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

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

19 “(A) appropriate staff of the Food and
 20 Drug Administration;

21 “(B) the Steering Committee;

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

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

4 “(E) academics or board-certified and li-
 5 censed medical clinicians with expertise in
 6 treating a rare disease or condition; and

7 “(F) other appropriate stakeholders.

8 “(6) POST-MEETING REPORTS.—

9 “(A) IN GENERAL.—Not later than 180
 10 days after an EL–SFDD meeting, the Founda-
 11 tion shall make publicly available on the website
 12 of the Food and Drug Administration—

13 “(i) a transcript and recording of the
 14 meeting; and

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

21 “(B) CONTENTS.—Each publication under
 22 subparagraph (A) shall include a clear identi-
 23 fication of—

24 “(i) areas of consensus;

1 “(ii) areas where additional clarifica-
2 tion or information is needed to reach con-
3 sensus; and

4 “(iii) next steps agreed upon with the
5 Food and Drug Administration.

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

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

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

17 “(2) to require the Food and Drug Administra-
18 tion to participate in additional meetings described
19 in paragraph (1);

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

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

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

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

10 “(7) to increase the number of review cycles for
11 drugs.

12 “(e) DEFINITIONS.—In this section:

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

16 “(2) The term ‘rare disease or condition’ has
17 the meaning given such term in section 526.

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

22 “(f) AUTHORIZATION OF APPROPRIATIONS.—

23 “(1) IN GENERAL.—To carry out this section,
24 there is authorized to be appropriated \$1,000,000
25 for each of fiscal years 2025 through 2029.

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—

14 “(1) a statement of whether any EL–SFDD
 15 meeting under section 770A was held that was rel-
 16 evant to such approval or licensure; and

17 “(2) if a meeting described in paragraph (1)
 18 was held, a description of how the Secretary incor-
 19 porated input from such meeting in the risk-benefit
 20 assessment described in section 505(d).

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

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

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

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

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

9 “(A) deliberations throughout the drug de-
 10 velopment lifecycle;

11 “(B) regulatory decision-making; and

12 “(C) formulating recommendations for fu-
 13 ture meetings.

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

17 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
 18 carry out this section, there is authorized to be appro-
 19 priated \$1,000,000 for each of fiscal years 2025 through
 20 2029.”.

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