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118TH CONGRESS
1ST SESSION

H. R. 5269

To amend the Federal Food, Drug, and Cosmetic Act to provide for the establishment and maintenance of a Pediatric Research Site Network.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 25, 2023

Mr. CURTIS (for himself and Mr. TONKO) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the establishment and maintenance of a Pediatric Research Site Network.

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 ''Pediatric Network Support Act''.

SEC. 2. PEDIATRIC RESEARCH SITE NETWORK.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524C. PEDIATRIC RESEARCH SITE NETWORK.

''(a) ESTABLISHMENT.—The Secretary shall provide for the establishment and maintenance of a Pediatric Research Site Network in which—

''(1) the Secretary awards grants to eligible entities; and

''(2) through such grants, the eligible entities collaborate on—

''(A) the development and dissemination of guidance and educational materials for the purposes of—

''(i) enhancing pediatric clinical trials, including with respect to pediatric study design and feasibility;

''(ii) identifying and mitigating challenges in pediatric research that delay pediatric clinical trials;

''(iii) best practices in the conduct of pediatric clinical trials;

''(iv) improving the process for the development of medical products;

''(v) labeling innovative medical products;

''(vi) accelerating medical product development; and

"(vii) enhancing medical product safety; and

"(B) such other activities as may be determined by the Secretary for purposes of enhancing pediatric clinical trials.

"(b) ELIGIBLE ENTITY.—To be eligible to receive a grant under this section, an entity shall meet each of the following:

"(1) The entity is—

"(A) an institution of higher education as defined in subsection (a) or (b) of section 101 of the Higher Education Act of 1965; or

"(B) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code.

"(2) The entity has experienced personnel, and clinical and other technical expertise, in the biomedical sciences.

"(3) The entity demonstrates to the Secretary's satisfaction that the entity is capable of carrying out the activities described in subsection (a)(2).

"(c) ANNUAL REPORT.—Not later than 18 months after the date of enactment of this section, and annually thereafter, the Secretary, in collaboration with the grant-

ees under this section, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

''(1) reviewing the operations and activities of the Pediatric Research Site Network in the previous year; and

''(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

''(d) DEFINITION.—In this section, the term 'medical product' means a drug (including a biological product), a device (including a diagnostic test), and any combination product described in section 503(g).

''(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $2,000,000 for each of fiscal years 2024 through 2029.''.

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