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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to authorize a program to support the adoption of, and improve the development of, innovative approaches to pharmaceutical product design and manufacturing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. LEVIN of California introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize a program to support the adoption of, and improve the development of, innovative approaches to pharmaceutical product design and manufacturing, 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 ''Drug Manufacturing Innovation Act of 2022''.

SEC. 2. EMERGING TECHNOLOGY PROGRAM.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.) is amended by inserting after section 566 of such Act (21 U.S.C. 360bbb–5) the following:

"SEC. 566A. EMERGING TECHNOLOGY PROGRAM.

"(a) PROGRAM ESTABLISHMENT.—

"(1) IN GENERAL.—The Secretary shall establish a program to support the adoption of, and improve the development of, innovative approaches to pharmaceutical product design and manufacturing.

"(2) ACTIONS.—In carrying out the program under paragraph (1), the Secretary may—

"(A) facilitate and increase communication between public and private entities, consortia, and individuals with respect to innovative pharmaceutical product design and manufacturing;

"(B) solicit information regarding, and conduct or support research on, innovative approaches to pharmaceutical product design and manufacturing;

"(C) convene meetings with representatives of industry, academia, other Federal agencies, international agencies, and other interested persons, as appropriate;

''(D) convene working groups to support pharmaceutical product design and manufacturing research and development;

''(E) support education and training for regulatory staff and scientists related to innovative approaches to pharmaceutical product design and manufacturing;

''(F) conduct research and testing to develop or validate innovative approaches to pharmaceutical product design and manufacturing;

''(G) advance regulatory science related to the development and review of innovative approaches to pharmaceutical product design and manufacturing;

''(H) convene working groups to support the harmonization of international regulatory requirements related to innovative approaches to pharmaceutical product design and manufacturing; and

''(I) award grants or contracts to carry out or support the program under paragraph (1).

''(3) GRANTS AND CONTRACTS.—To seek a grant or contract under this section, an entity shall submit an application—

''(A) in such form and manner as the Secretary may require; and

''(B) containing such information as the Secretary may require, including a description of—

''(i) how the entity will conduct the activities to be supported through the grant or contract; and

''(ii) how such activities will further research and development related to, or adoption of, innovative approaches to pharmaceutical product design and manufacturing.

''(b) GUIDANCE.—The Secretary shall—

''(1) issue or update guidance to help facilitate the adoption of, and advance the development of, innovative approaches to pharmaceutical product design and manufacturing; and

''(2) include in such guidance descriptions of—

''(A) any regulatory requirements related to the development or review of technologies related to innovative approaches to pharmaceutical product design and manufacturing, including regulatory requirements necessary for

updates and improvements to such technologies after product approval; and

''(B) data required to demonstrate the identity, safety, purity, and potency of drugs manufactured using such technologies.

''(c) REPORT TO CONGRESS.— Not later than 4 years after the date of enactment of this section, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

''(1) an annual accounting of the allocation of funds made available to carry out this section;

''(2) the number of full-time equivalent staff dedicated to the program under subsection (a)(1);

''(3) the number of meetings held by the Food and Drug Administration, including meetings convened as part of a working group described in subparagraph (D) or (H) of paragraph (2) of subsection (a), and the topics of each such meeting; and

''(4) the number of products approved or licensed, after the date of enactment of this section, using an innovative approach to pharmaceutical product design and manufacturing.

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $20,000,000 for each fiscal year 2023 through 2027.''.