

.....  
(Original Signature of Member)

117TH CONGRESS  
2D SESSION

# **H. R. 6988**

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.

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 “Drug Manufacturing  
5       Innovation Act of 2022”.

1 **SEC. 2. EMERGING TECHNOLOGY PROGRAM.**

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

6 **“SEC. 566A. EMERGING TECHNOLOGY PROGRAM.**

7 “(a) PROGRAM ESTABLISHMENT.—

8 “(1) IN GENERAL.—The Secretary shall estab-  
9 lish a program to support the adoption of, and im-  
10 prove the development of, innovative approaches to  
11 pharmaceutical product design and manufacturing.

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

14 “(A) facilitate and increase communication  
15 between public and private entities, consortia,  
16 and individuals with respect to innovative phar-  
17 maceutical product design and manufacturing;

18 “(B) solicit information regarding, and  
19 conduct or support research on, innovative ap-  
20 proaches to pharmaceutical product design and  
21 manufacturing;

22 “(C) convene meetings with representatives  
23 of industry, academia, other Federal agencies,  
24 international agencies, and other interested per-  
25 sons, as appropriate;

1           “(D) convene working groups to support  
2           pharmaceutical product design and manufac-  
3           turing research and development;

4           “(E) support education and training for  
5           regulatory staff and scientists related to innova-  
6           tive approaches to pharmaceutical product de-  
7           sign and manufacturing;

8           “(F) conduct research and testing to de-  
9           velop or validate innovative approaches to phar-  
10          maceutical product design and manufacturing;

11          “(G) advance regulatory science related to  
12          the development and review of innovative ap-  
13          proaches to pharmaceutical product design and  
14          manufacturing;

15          “(H) convene working groups to support  
16          the harmonization of international regulatory  
17          requirements related to innovative approaches  
18          to pharmaceutical product design and manufac-  
19          turing; and

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

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

1           “(A) in such form and manner as the Sec-  
2           retary may require; and

3           “(B) containing such information as the  
4           Secretary may require, including a description  
5           of—

6                   “(i) how the entity will conduct the  
7                   activities to be supported through the  
8                   grant or contract; and

9                   “(ii) how such activities will further  
10                  research and development related to, or  
11                  adoption of, innovative approaches to phar-  
12                  maceutical product design and manufac-  
13                  turing.

14           “(b) GUIDANCE.—The Secretary shall—

15                   “(1) issue or update guidance to help facilitate  
16                   the adoption of, and advance the development of, in-  
17                   novative approaches to pharmaceutical product de-  
18                   sign and manufacturing; and

19                   “(2) include in such guidance descriptions of—

20                           “(A) any regulatory requirements related  
21                           to the development or review of technologies re-  
22                           lated to innovative approaches to pharma-  
23                           ceutical product design and manufacturing, in-  
24                           cluding regulatory requirements necessary for

1 updates and improvements to such technologies  
2 after product approval; and

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

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

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

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

16 “(3) the number of meetings held by the Food  
17 and Drug Administration, including meetings con-  
18 vened as part of a working group described in sub-  
19 paragraph (D) or (H) of paragraph (2) of subsection  
20 (a), and the topics of each such meeting; and

21 “(4) the number of products approved or li-  
22 censed, after the date of enactment of this section,  
23 using an innovative approach to pharmaceutical  
24 product design and manufacturing.

1       “(d) AUTHORIZATION OF APPROPRIATIONS.—To  
2 carry out this section, there is authorized to be appro-  
3 priated \$20,000,000 for each fiscal year 2023 through  
4 2027.”.