

AMENDMENT NO. _____ Calendar No. _____

Purpose: To establish an emerging pathogen preparedness program within the Food and Drug Administration to improve regulatory oversight of medical countermeasures for future pandemics.

IN THE SENATE OF THE UNITED STATES—118th Cong., 1st Sess.

S. _____

To reauthorize certain programs under the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. HICKENLOOPER
(for himself and Mr. BUDD)

Viz:

1 At the appropriate place in title II, insert the fol-
2 lowing:

3 **SEC. 2_____ . EMERGING PATHOGENS PREPAREDNESS PRO-**
4 **GRAM.**

5 (a) IN GENERAL.—Section 565 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amend-
7 ed by adding at the end the following:

8 “(j) EMERGING PATHOGENS PREPAREDNESS PRO-
9 GRAM.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish a program to facilitate the development, review,
3 licensure, approval, and clearance of counter-
4 measures, and products that could potentially be
5 countermeasures, under the jurisdiction of the Cen-
6 ter for Biologics Evaluation and Research.

7 “(2) ACTIVITIES.—The activities of the pro-
8 gram established under paragraph (1) may include,
9 either directly or by grant, contract, or cooperative
10 agreement, the following:

11 “(A) Any activities described in subsection
12 (b).

13 “(B) Activities to advance scientific re-
14 search related to the development of tools,
15 standards, and approaches to assess the safety,
16 efficacy, quality, and performance of counter-
17 measures.

18 “(C) Activities to maintain or enhance sur-
19 veillance programs that monitor counter-
20 measures.

21 “(D) Activities to help ensure blood safety
22 and availability.

23 “(E) Prioritizing the research and develop-
24 ment of platform vaccine technologies to sup-
25 port an emergency use authorization request

1 under section 564 or an application under
2 351(a) of the Public Health Service Act.

3 “(F) Such other activities as the Secretary
4 determines necessary or appropriate.

5 “(3) RULE OF CONSTRUCTION.—Nothing in
6 this subsection shall be construed to alter the au-
7 thority of the Secretary to license, approve, clear, or
8 authorize countermeasures, including biological prod-
9 ucts, pursuant to section 351 of the Public Health
10 Service Act or section 505 or 564 of this Act, in-
11 cluding standards of evidence and applicable condi-
12 tions for licensure, approval, clearance, or authoriza-
13 tion.”.

14 (b) AUTHORIZATION OF APPROPRIATIONS.—To carry
15 out subsection (j) of section 565 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 360bbb-4), as added
17 by subsection (a), there are authorized to be appropriated
18 such sums as may be necessary for each of fiscal years
19 2024 through 2028.