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:

At the appropriate place in title II, insert the following:

SEC. 2_____. EMERGING PATHOGENS PREPAREDNESS PROGRAM.

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

''(j) EMERGING PATHOGENS PREPAREDNESS PROGRAM.—

"(1) IN GENERAL.—The Secretary shall establish a program to facilitate the development, review, licensure, approval, and clearance of countermeasures, and products that could potentially be countermeasures, under the jurisdiction of the Center for Biologics Evaluation and Research.

"(2) ACTIVITIES.—The activities of the program established under paragraph (1) may include, either directly or by grant, contract, or cooperative agreement, the following:

"(A) Any activities described in subsection (b).

"(B) Activities to advance scientific research related to the development of tools, standards, and approaches to assess the safety, efficacy, quality, and performance of countermeasures.

"(C) Activities to maintain or enhance surveillance programs that monitor countermeasures.

"(D) Activities to help ensure blood safety and availability.

"(E) Prioritizing the research and development of platform vaccine technologies to support an emergency use authorization request

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

"(F) Such other activities as the Secretary determines necessary or appropriate.

"(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter the authority of the Secretary to license, approve, clear, or authorize countermeasures, including biological products, pursuant to section 351 of the Public Health Service Act or section 505 or 564 of this Act, including standards of evidence and applicable conditions for licensure, approval, clearance, or authorization.".

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