

[DISCUSSION DRAFT]118TH CONGRESS
1ST SESSION**H. R.** _____

To amend the Public Health Service Act to treat as a national security priority the public health situational awareness and disease detection network, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M____. _____ introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend the Public Health Service Act to treat as a national security priority the public health situational awareness and disease detection network, 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 “Biosecurity Infrastruc-
5 ture for Operational Early Warning Act of 2023” or the
6 “BIO Early Warning Act of 2023”.

1 **SEC. 2. SITUATIONAL AWARENESS AND DISEASE DETEC-**
2 **TION AS A NATIONAL SECURITY PRIORITY.**

3 Paragraph (8) of section 319D(c) of the Public
4 Health Service Act (42 U.S.C. 247d–4(c)) is amended to
5 read as follows:

6 “(8) SITUATIONAL AWARENESS AND DISEASE
7 DETECTION AS A NATIONAL SECURITY PRIORITY.—

8 “(A) MEETINGS.—The Secretary, on a
9 periodic basis as applicable and appropriate,
10 shall consult with the Director of National In-
11 telligence to inform the development and capa-
12 bilities of the public health situational aware-
13 ness and disease detection network.

14 “(B) REPORTS.—Not later than 12
15 months after the date of enactment of this
16 paragraph and annually thereafter, the Sec-
17 retary, in consultation with the Director of Na-
18 tional Intelligence, shall prepare and submit—

19 “(i) a report on the progress toward
20 implementation of the public health situa-
21 tional awareness and disease detection net-
22 work to the Committee on Energy and
23 Commerce of the House of Representatives
24 and the Committee on Health, Education,
25 Labor, and Pensions of the Senate; and

1 “(ii) a classified annex to such report
2 to the Permanent Select Committee on In-
3 telligence of the House of Representatives
4 and the Select Committee on Intelligence
5 of the Senate.”.

6 **SEC. 3. STRATEGIC NATIONAL STOCKPILE AND SECURITY**
7 **COUNTERMEASURE PROCUREMENTS.**

8 Section 319F–2(a) of the Public Health Service Act
9 (42 U.S.C. 247d–6b(a)) is amended—

10 (1) in paragraph (2)(B), by striking “each new
11 or modified countermeasure procurement or replen-
12 ishment” and inserting “each new or modified coun-
13 termeasure, medical device, or ancillary medical sup-
14 ply procurement or replenishment”;

15 (2) in paragraph (2)(B)(i)—

16 (A) in subclause (VII), strike “and” at the
17 end; and

18 (B) by adding at the end the following:

19 “(IX) an assessment of the quan-
20 tities of medical devices and ancillary
21 medical supplies needed in the stock-
22 pile for the safe collection, storage,
23 and transportation of related patho-
24 gen samples for testing, sequencing,

1 and research on and development of
2 countermeasures; and”; and

3 (3) in paragraph (3)—

4 (A) in subparagraph (J), by striking “and”
5 at the end;

6 (B) in subparagraph (K), by striking the
7 period at the end and inserting “; and”; and

8 (C) by adding at the end the following:

9 “(L) ensure the availability of medical de-
10 vices, ancillary medical supplies, and other ad-
11 vanced technologies for the safe collection, stor-
12 age, and transportation of related pathogen
13 samples for testing, sequencing, and research
14 on and development of countermeasures.”.

15 **[SEC. 4. INCLUSION OF A BIOLOGICAL ATTRIBUTION**
16 **STRATEGY IN THE NATIONAL HEALTH SECU-**
17 **RITY STRATEGY.]**

18 Section 2811 of the Public Health Service Act (42
19 U.S.C. 300hh–10) is amended by adding at the end the
20 following:】

21 **【“(h) BIOLOGICAL ATTRIBUTION STRATEGY.—】**

22 **【“(1) IN GENERAL.—The National Health Se-**
23 **curity Strategy under section 2802 shall include a**
24 **biological attribution strategy developed in accord-**
25 **ance with this subsection.】**

1 【“(2) DEVELOPMENT.—The Assistant Sec-
2 retary for Preparedness and Response, in consulta-
3 tion with the heads of the appropriate Federal agen-
4 cies, shall develop a biological attribution strategy.】

5 【“(3) CONTENTS.—The biological attribution
6 strategy under this subsection shall include the fol-
7 lowing:】

8 【“(A) A description of the biological attri-
9 bution duties of each appropriate Federal offi-
10 cial, including identification of—】

11 【“(i) the extent and nature of involve-
12 ment, if any, of the appropriate Federal offi-
13 cial in the collection, analysis, or distribu-
14 tion of intelligence, or other information,
15 relevant to the attribution of biological
16 events, including any interagency coordina-
17 tion functions related to such collection,
18 analysis, or distribution;】

19 【“(ii) the level and type of biological
20 events that may trigger an attribution de-
21 termination by the appropriate Federal offi-
22 cials regarding the source, cause, or ori-
23 gin of the event; and】

24 【“(iii) the process of the appropriate
25 Federal officials for making an attribution

1 determination as specified in subparagraph
2 (B).】

3 【“(B) The extent to which, in making such
4 an attribution determination, the appropriate
5 Federal officials shall—】

6 【“(i) ensure the accuracy, reliability,
7 timeliness, credibility, and defensibility of
8 such intelligence, information, and evi-
9 dence, including by meeting applicable evi-
10 dentiary standards; and】

11 【“(ii) address national security con-
12 siderations.】

13 【“(4) DEFINITION.—In this subsection, the
14 term ‘appropriate Federal official’ means each of the
15 following:】

16 【“(A) The Secretary of Agriculture.】

17 【“(B) The Secretary of Defense.】

18 【“(C) The Secretary of Energy.】

19 【“(D) The Secretary of Health and
20 Human Services.】

21 【“(E) The Secretary of Homeland Secu-
22 rity.】

23 【“(F) The Secretary of the Interior.】

24 【“(G) The Secretary of State.】

25 【“(H) The Secretary of Treasury.】

1 【“(I) The Secretary of Veterans Affairs.”】

2 【“(J) The Attorney General.”】

3 【“(K) The Director of National Intel-
4 ligence.”】

5 【“(L) The Director of the Central Intel-
6 ligence Agency and the heads of the other ele-
7 ments of the intelligence community.”】

8 【“(d) NOTIFICATION REGARDING FOREIGN CO-
9 OPERATION.—In the case of an outbreak or potential out-
10 break of a disease with pandemic potential in a foreign
11 country, the Assistant Secretary for Preparedness and Re-
12 sponse, in consultation with the heads of the appropriate
13 Federal agencies, shall make a determination as to wheth-
14 er the country is cooperative or uncooperative with respect
15 to—】

16 【“(1) notifying the United States of the out-
17 break or potential outbreak;】

18 【“(2) sharing scientific data; and】

19 【“(3) otherwise responding to the outbreak or
20 potential outbreak.”.】

21 **SEC. 5. COORDINATION OF HHS EARLY WARNING AND DIS-**
22 **EASE DETECTION PROGRAMS.**

23 (a) IN GENERAL.—Section 2811 of the Public Health
24 Service Act (42 U.S.C. 300hh–10(b)), as amended, is fur-
25 ther amended—

1 (1) in subsection (b), by adding at the end the
2 following:

3 “(8) EARLY WARNING.—Coordinate and [over-
4 see] all disease detection programs for the Sec-
5 retary, including the early warning program estab-
6 lished under section 2816 .”; and

7 (2) in subsection (c)(2)—

8 (A) in subparagraph (E), by striking
9 “and” at the end;

10 (B) in subparagraph (F), by inserting
11 “and” after the semicolon; and

12 (C) by adding at the end the following:

13 “(G) all early warning and disease detec-
14 tion programs within the Department of Health
15 and Human Services, including the National
16 Syndromic Surveillance Program, the Sequenc-
17 ing for Public Health Emergency Response, Ep-
18 idemiology, and Surveillance, the Center for
19 Forecasting and Outbreak Analytics, the Lab-
20 oratory Response Network, the Epidemic Intel-
21 ligence Service, and the Global Disease Detec-
22 tion Operations Center;”.

23 (b) EARLY WARNING FOR DISEASE DETECTION AND
24 PREPAREDNESS.—Subtitle B of title XXVIII of the Public

1 Health Service Act (42 U.S.C. 300hh–10 et seq.) is
2 amended by adding at the end the following:

3 **“SEC. 2816. EARLY WARNING FOR DISEASE DETECTION AND**
4 **PREPAREDNESS.**

5 “(a) PLAN.—

6 “(1) IN GENERAL.—The Assistant Secretary for
7 Preparedness and Response shall develop and submit
8 to the appropriate committees of Congress an an-
9 nual strategy and accompanying implementation
10 plan, to be known as the Early Warning and Disease
11 Detection Strategy and Implementation Plan, for—

12 “(A) the deployment of an early warning
13 function; and

14 “(B) the coordination of ongoing disease
15 detection activities, including sample collection,
16 testing, sequencing, reporting, and dissemina-
17 tion of pathogen data.

18 “(2) OBJECTIVES.—The objectives of the Early
19 Warning and Disease Detection Strategy and Imple-
20 mentation Plan shall include—

21 “(A) development of a robust early warn-
22 ing function for the United States which incor-
23 porates diagnostic testing, genomic sequencing,
24 epidemiological data analysis, community detec-

1 tion activities, and other appropriate tech-
2 nologies;

3 “(B) identification of known pathogens
4 and new variants of such pathogens;

5 “(C) identification of new threats at the
6 earliest time to inform public health strategies;

7 “(D) understanding of the prevalence of
8 disease outbreaks and currently circulating in-
9 fections;

10 “(E) ongoing active sample collection from
11 broad sources including wastewater, airports,
12 and transportation hubs;

13 “(F) ongoing sample collection from pa-
14 tient sources including emergency rooms, ur-
15 gent care centers, and other provider settings;

16 “(G) deployment of novel disease detection
17 technologies, including multiplex assays and
18 genomic sequencing, with an emphasis on tech-
19 nologies deployed during the COVID–19 pan-
20 demic;

21 “(H) the ability to rapidly deploy testing,
22 data analytics, and sequencing technologies at
23 scale during a public health event; and

24 “(I) coordination of disease data collected
25 throughout the United States.

1 “(3) CONSULTATION.—In developing the Early
2 Warning and Disease Detection Strategy and Imple-
3 mentation Plan, the Assistant Secretary for Pre-
4 paredness and Response shall consult with State and
5 local public health entities and private sector part-
6 ners.

7 “(b) COORDINATION AND ELIMINATING DUPLICA-
8 TION.—

9 “(1) CONSULTATION.—In developing the Early
10 Warning and Disease Detection Strategy and Imple-
11 mentation Plan, the Assistant Secretary for Pre-
12 paredness and Response shall consult with—

13 “(A) the Director of the Centers for Dis-
14 ease Control and Prevention;

15 “(B) the Secretary of Defense;

16 “(C) the Secretary of Veteran Affairs;

17 “(D) the Secretary of Homeland Security;

18 “(E) the Administrator of the Environ-
19 mental Protection Agency;

20 “(F) the Secretary of Agriculture;

21 “(G) the Secretary of State;

22 “(H) the Secretary of Homeland Security;

23 and

24 “(I) other Federal officials as appropriate.

1 “(2) PURPOSES.—The purposes of consultation
2 under paragraph (1) shall be to coordinate disease
3 detection activities, streamline Federal programs,
4 and eliminate waste and duplication.

5 “(c) PUBLIC-PRIVATE PARTNERSHIPS.—

6 “(1) AWARDS.—In carrying out the Early
7 Warning and Disease Detection Strategy and Imple-
8 mentation Plan, the Secretary shall award competi-
9 tive grants or cooperative agreements to eligible enti-
10 ties to enable such entities to conduct screening, de-
11 tection, testing, data analytics, or sequencing of pub-
12 lic health threats or potential pandemic pathogens to
13 provide an early warning capability for public health
14 emergencies.

15 “(2) ELIGIBILITY.—To be eligible for an award
16 under paragraph (1), an entity shall be—

17 “(A) a State or local laboratory, a com-
18 mercial laboratory, an academic laboratory, or a
19 diagnostic testing, data analytics, or sequencing
20 device manufacturer; and

21 “(B) capable of screening, detecting, test-
22 ing, or sequencing for public health threats or
23 potential pandemic pathogens.

24 “(3) APPLICATION.—To seek an award under
25 paragraph (1), an eligible entity shall submit to the

1 Secretary an application at such time, in such man-
2 ner, and containing such information as the Sec-
3 retary may require.

4 “(4) USE OF FUNDS.—An award under para-
5 graph (1) shall be used for activities described in
6 such paragraph related to the following early warn-
7 ing and disease detection goals:

8 “(A) Active detection of public health
9 threats or potential pandemic pathogens
10 through the collection, testing, and analysis of
11 samples in wastewater, at airports and other
12 transportation hubs, in community settings, and
13 by other methods and locations as deemed ap-
14 propriate by the Secretary.

15 “(B) Passive detection of public health
16 threats or potential pandemic pathogens by col-
17 lection and testing of samples at hospitals,
18 emergency room departments, urgent care cen-
19 ters, and other point-of-care facilities as deemed
20 appropriate by the Secretary.

21 “(C) Creation of real-time pathogen se-
22 quence data and molecular epidemiology of col-
23 lected samples.

24 “(5) REGIONAL COORDINATION.—In making
25 awards under paragraph (1), the Secretary shall give

1 preference to eligible entities that submit applica-
2 tions that, in the determination of the Secretary, will
3 enhance coordination among the officials listed in
4 subsection (b)(1).

5 “(6) COORDINATION WITH LOCAL EARLY WARN-
6 ING CAPABILITIES.—An eligible entity shall, to the
7 extent practicable, ensure that activities carried out
8 through an award under paragraph (1) are coordi-
9 nated with disease detection activities of relevant
10 State and local public health entities.

11 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
12 carry out this section, there is authorized to be appro-
13 priated [\$_____] for fiscal years 2024 through
14 2028.”.