

[DISCUSSION DRAFT]

115TH CONGRESS
2D SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mrs. BROOKS of Indiana introduced the following bill; which was referred to the Committee on _____

A BILL

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, 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 “Pandemic and All-Haz-
5 ards Preparedness Reauthorization Act of 2018”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.

TITLE I—STRENGTHENING NATIONAL PREPAREDNESS AND
RESPONSE FOR PUBLIC HEALTH EMERGENCIES

- Sec. 101. Coordination of preparedness for and response to all-hazards public health emergencies.
- Sec. 102. Public health emergency medical countermeasures enterprise.
- Sec. 103. National Advisory Committee on Children and Disasters.
- Sec. 104. National Disaster Medical System Personnel.
- Sec. 105. Volunteer Medical Reserve Corps.
- Sec. 106. Continuing the role of the Department of Veterans Affairs.

TITLE II—OPTIMIZING STATE AND LOCAL ALL-HAZARDS
PREPAREDNESS AND RESPONSE

- Sec. 201. Public health emergencies.
- Sec. 202. Improving State and local public health security.
- Sec. 203. Partnerships for State and regional hospital preparedness to improve surge capacity.
- Sec. 204. Revitalizing the Centers for Disease Control and Prevention.
- Sec. 205. Authorization of appropriations for Emergency System for Advanced Registration of Volunteer Health Professionals.

TITLE III—ACCELERATING MEDICAL COUNTERMEASURE
ADVANCED RESEARCH AND DEVELOPMENT

- Sec. 301. Strategic national stockpile and security countermeasure procurement.
- Sec. 302. Biomedical advanced research and development authority.

TITLE IV—MISCELLANEOUS PROVISIONS

- Sec. 401. Cybersecurity.
- Sec. 402. Miscellaneous FDA amendments.

1 **TITLE I—STRENGTHENING NA-**
 2 **TIONAL PREPAREDNESS AND**
 3 **RESPONSE FOR PUBLIC**
 4 **HEALTH EMERGENCIES**

5 **SEC. 101. COORDINATION OF PREPAREDNESS FOR AND RE-**
 6 **SPONSE TO ALL-HAZARDS PUBLIC HEALTH**
 7 **EMERGENCIES.**

8 Section 2811 of the Public Health Service Act (42
 9 U.S.C. 300hh–10) is amended—

1 (1) in subsection (b)(4)(G), by inserting “the
2 pandemic influenza and emerging infectious disease
3 program established under section 319L(d), or” be-
4 fore “all-hazards medical and public health pre-
5 paredness and response”; and

6 (2) in subsection (b)(7), by inserting “the re-
7 search and development activities of the pandemic
8 influenza and emerging infectious disease program
9 established under section 319L(d) with respect to
10 qualified pandemic or epidemic products (as defined
11 in section 319F–3), and” before “the medical coun-
12 termeasure priorities described in subsection (d)”.

13 **SEC. 102. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
14 **TERMEASURES ENTERPRISE.**

15 Subtitle B of title XXVIII of the Public Health Serv-
16 ice Act (42 U.S.C. 300hh-10 et seq.) is amended—

17 (1) by redesignating section 2811A as 2811B;
18 and

19 (2) by inserting after section 2811 the fol-
20 lowing:

21 **“SEC. 2811A. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
22 **TERMEASURES ENTERPRISE.**

23 “(a) IN GENERAL.—The Secretary shall establish
24 and the Assistant Secretary for Preparedness and Re-
25 sponse may convene an interagency panel of advisors to

1 be known as the Public Health Emergency Medical Coun-
2 termeasures Enterprise (in this section referred to as the
3 ‘PHEMCE’).

4 “(b) MEMBERS.—In addition to the Assistant Sec-
5 retary for Preparedness and Response, who shall serve as
6 Chair, the PHEMCE shall include the following members:

7 “(1) The Director of the Biomedical Advanced
8 Research and Development Authority (or the Direc-
9 tor’s designee).

10 “(2) The Director of the Centers for Disease
11 Control and Prevention (or the Director’s designee).

12 “(3) The Director of the National Institutes of
13 Health (or the Director’s designee).

14 “(4) The Commissioner of Food and Drugs (or
15 the Commissioner’s designee).

16 “(5) The Secretary of Defense (or the Sec-
17 retary’s designee).

18 “(6) The Secretary of Homeland Security (or
19 the Secretary’s designee).

20 “(7) The Secretary of Agriculture (or the Sec-
21 retary’s designee).

22 “(8) The Secretary of Veterans Affairs (or the
23 Secretary’s designee).

1 “(9) Representatives of any other Federal agen-
2 cies, as the Assistant Secretary for Preparedness
3 and Response determines appropriate.

4 “(c) FUNCTIONS.—The PHEMCE shall—

5 “(1) advise the Assistant Secretary for Pre-
6 paredness and Response regarding research, develop-
7 ment, and procurement of security countermeasures
8 (as defined in section 319F–2(c)) based on the
9 health security needs of the United States; and

10 “(2) assist the Assistant Secretary for Pre-
11 paredness and Response in the identification of gaps
12 in public health preparedness and response related
13 to such security countermeasures and challenges to
14 addressing such needs (including any regulatory
15 challenges).”.

16 **SEC. 103. NATIONAL ADVISORY COMMITTEE ON CHILDREN**
17 **AND DISASTERS.**

18 Subsection (f) of section 2811B of the Public Health
19 Service Act (42 U.S.C. 300hh–10a), as redesignated by
20 section 102, is amended by striking “2018” and inserting
21 “2023”.

22 **SEC. 104. NATIONAL DISASTER MEDICAL SYSTEM PER-**
23 **SONNEL.**

24 (a) DIRECT HIRE AUTHORITY.—Section 2812(c)(1)
25 of the Public Health Service Act (42 U.S.C. 300hh–

1 11(c)(1)) is amended by striking “in accordance with ap-
2 plicable civil service laws and regulations” and inserting
3 “without regard to those provisions of title 5, United
4 States Code, governing appointments in the competitive
5 service”.

6 (b) DEATH BENEFITS.—Section 1204(9) of the Om-
7 nibus Crime Control and Safe Streets Act of 1968 (34
8 U.S.C. 10284(9)) is amended—

9 (1) in subparagraph (C), by striking “or” at
10 the end;

11 (2) in subparagraph (D), by striking the period
12 at the end and inserting “; or”; and

13 (3) by adding at the end the following:

14 “(E) an individual appointed to assist the
15 National Disaster Medical System pursuant to
16 section 2812(c)(1) of the Public Health Service
17 Act.”.

18 (c) AUTHORIZATION OF APPROPRIATIONS.—Section
19 2812(g) of the Public Health Service Act (42 U.S.C.
20 300hh–11(g)) is amended by striking “\$52,700,000 for
21 each of fiscal years 2014 through 2018” and inserting
22 “\$57,400,000 for each of fiscal years 2019 through
23 2023”.

1 **SEC. 105. VOLUNTEER MEDICAL RESERVE CORPS.**

2 Section 2813 of the Public Health Service Act (42
3 U.S.C. 300hh-15)) is amended—

4 (1) in subsection (a), by striking the second
5 sentence (requiring appointment of a director); and

6 (2) in subsection (i), by striking “\$11,200,000
7 for each of fiscal years 2014 through 2018” and in-
8 serting “\$6,000,000 for each of fiscal years 2019
9 through 2023”.

10 **SEC. 106. CONTINUING THE ROLE OF THE DEPARTMENT OF**
11 **VETERANS AFFAIRS.**

12 Section 8117(g) of title 38, United States Code, is
13 amended by striking “\$155,300,000 for each of fiscal
14 years 2014 through 2018” and inserting “\$126,800,000
15 for each of fiscal years 2019 through 2023”.

16 **TITLE II—OPTIMIZING STATE**
17 **AND LOCAL ALL-HAZARDS**
18 **PREPAREDNESS AND RE-**
19 **SPONSE**

20 **SEC. 201. PUBLIC HEALTH EMERGENCIES.**

21 (a) **RESPONSE FUND.**—Section 319 of the Public
22 Health Service Act (42 U.S.C. 247d) is amended—

23 (1) by amending subsection (b) to read as fol-
24 lows:

25 “(b) **PUBLIC HEALTH EMERGENCY RESPONSE**
26 **FUND.**—

1 “(1) ESTABLISHMENT.—There is established in
2 the Treasury a fund to be designated as the ‘Public
3 Health Emergency Response Fund’ (referred to in
4 this subsection as the ‘Fund’) to be made available
5 to the Secretary for the following purposes:

6 “(A) To carry out subsection (a) only if a
7 public health emergency has been declared by
8 the Secretary under such subsection.

9 “(B) To respond to a public health threat
10 or emergency that the Secretary determines has
11 significant potential—

12 “(i) to occur; and

13 “(ii) to affect national security or the
14 health and security of United States citi-
15 zens domestically or internationally.

16 “(C) To prevent, prepare for, or respond
17 to—

18 “(i) a chemical, biological, radio-
19 logical, or nuclear threat; or

20 “(ii) an emerging infectious disease.

21 “(D) To develop and procure medical
22 countermeasures for a chemical, biological, radi-
23 ological, or nuclear threat, or an emerging in-
24 fectious disease.

1 “(2) FUNDING.—The Secretary may transfer to
2 the Fund such amounts as are necessary from any
3 discretionary appropriations (pursuant to the Bal-
4 anced Budget and Emergency Deficit Control Act of
5 1985) made available in any appropriations Act,
6 provided that no such appropriation is reduced by
7 more than 1 percent. Any such transferred amounts
8 shall remain available until expended.

9 “(3) TRANSFER OF FUNDS TO OTHER AC-
10 COUNTS.—The Secretary may transfer amounts in
11 the Fund to other accounts in the Department of
12 Health and Human Services for the purposes de-
13 scribed in paragraph (1).

14 “(4) SUPPLEMENT NOT SUPPLANT.—

15 “(A) FUNDS.—Any amounts in the Fund
16 shall be used to supplement and not supplant
17 any other amounts provided for the purposes
18 described in paragraph (1).

19 “(B) TRANSFER AUTHORITIES.—The
20 transfer authority under this section is in addi-
21 tion to any other transfer authority otherwise
22 available to the Secretary.

23 “(5) STRATEGIC NATIONAL STOCKPILE.—Any
24 product purchased using amounts in the Fund may,
25 at the discretion of the Secretary, be maintained in

1 the Strategic National Stockpile under section
2 319F-2.

3 “(6) REPORT.—Not later than 90 days after
4 the end of each fiscal year, the Secretary shall pre-
5 pare and submit to the Committee on Health, Edu-
6 cation, Labor, and Pensions and the Committee on
7 Appropriations of the Senate and the Committee on
8 Energy and Commerce and the Committee on Ap-
9 propriations of the House of Representatives a re-
10 port describing—

11 “(A) the expenditures made from the Fund
12 in such fiscal year;

13 “(B) each public health emergency for
14 which expenditures were made and the activities
15 undertaken with respect to each such emer-
16 gency; and

17 “(C) any unobligated balances in the Fund
18 and all obligations incurred for such fiscal year,
19 including obligations by program, project, or ac-
20 tivity.”;

21 (2) by striking subsection (e); and

22 (3) by redesignating subsections (d) through (f)
23 as subsections (c) through (e), respectively.

24 (b) TEMPORARY REASSIGNMENT OF FEDERALLY
25 FUNDED PERSONNEL.—Subsection (d)(8) of section 319

1 of the Public Health Service Act (42 U.S.C. 247d), as re-
2 designated by subsection (a)(3), is amended by striking
3 “2018” and inserting “2023”.

4 **SEC. 202. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
5 **SECURITY.**

6 Section 319C–1(h)(1)(A) of the Public Health Serv-
7 ice Act (42 U.S.C. 247d–3a(h)(1)(A)) is amended by
8 striking “\$641,900,000 for fiscal year 2014 for awards
9 pursuant to paragraph (3) (subject to the authority of the
10 Secretary to make awards pursuant to paragraphs (4) and
11 (5)), and \$641,900,000 for each of fiscal years 2015
12 through 2018” and inserting “\$670,000,000 for each of
13 fiscal years 2019 through 2023”.

14 **SEC. 203. PARTNERSHIPS FOR STATE AND REGIONAL HOS-**
15 **PITAL PREPAREDNESS TO IMPROVE SURGE**
16 **CAPACITY.**

17 (a) IN GENERAL.—Section 319C–2 of the Public
18 Health Service Act (42 U.S.C. 247d–3b) is amended—

19 (1) in the section heading, by striking “**HOS-**
20 **PITAL PREPAREDNESS**” and inserting “**HOS-**
21 **PITAL PREPAREDNESS AND RESPONSE**”; and

22 (2) by amending subsection (a) to read as fol-
23 lows:

1 “(a) IN GENERAL.—The Secretary shall award com-
2 petitive grants or cooperative agreements to eligible enti-
3 ties to enable such entities—

4 “(1) to improve surge capacity and enhance
5 community and hospital preparedness for public
6 health emergencies, including, as appropriate, capac-
7 ity and preparedness to address the needs of chil-
8 dren and other at-risk individuals; and

9 “(2) to implement response activities, including
10 a medical surge, in the event of such an emer-
11 gency.”.

12 (b) ELIGIBILITY.—Section 319C–2(b)(1)(A) of the
13 Public Health Service Act (42 U.S.C. 247d–3b(b)(1)(A))
14 is amended—

15 (1) in clause (ii), by striking “or” at the end;

16 (2) in clause (iii), by striking “and” at the end
17 and inserting “or”; and

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

19 “(iv) be a health coalition, State hospital
20 association, or a health system; and”.

21 (c) AUTHORIZATION OF APPROPRIATIONS.—Sub-
22 section (j) of section 319C–2 of the Public Health Service
23 Act (42 U.S.C. 247d–3b(j)) is amended in paragraph (1),
24 by striking “\$374,700,000 for each of fiscal years 2014

1 through 2018” and inserting “\$264,600,000 for each of
2 fiscal years 2019 through 2023”.

3 **SEC. 204. REVITALIZING THE CENTERS FOR DISEASE CON-**
4 **TROL AND PREVENTION.**

5 Section 319D(f) of the Public Health Service Act (42
6 U.S.C. 247d-4(f)) is amended by inserting by striking
7 “\$138,300,000 for each of fiscal years 2014 through
8 2018” and inserting “\$161,800,000 for each of fiscal
9 years 2019 through 2023”.

10 **SEC. 205. AUTHORIZATION OF APPROPRIATIONS FOR**
11 **EMERGENCY SYSTEM FOR ADVANCED REG-**
12 **ISTRATION OF VOLUNTEER HEALTH PROFES-**
13 **SIONALS.**

14 Section 319I(k) of the Public Health Service Act (42
15 U.S.C. 247d-7b) is amended by striking “fiscal years
16 2014 through 2018” and inserting “fiscal years 2019
17 through 2023”.

18 **TITLE III—ACCELERATING MED-**
19 **ICAL COUNTERMEASURE AD-**
20 **VANCED RESEARCH AND DE-**
21 **VELOPMENT**

22 **SEC. 301. STRATEGIC NATIONAL STOCKPILE AND SECURITY**
23 **COUNTERMEASURE PROCUREMENT.**

24 (a) IN GENERAL.—

1 (1) DELEGATION TO ASPR.—Subsection (a)(1)
2 of section 319F–2 of the Public Health Service Act
3 (42 U.S.C. 247d–6b) is amended by striking “in col-
4 laboration with the Director of the Centers for Dis-
5 ease Control and Prevention” and inserting “acting
6 through the Assistant Secretary for Preparedness
7 and Response”.

8 (2) CONFORMING AMENDMENTS.—Subsection
9 (c) of section 2811 of the Public Health Service Act
10 (42 U.S.C. 300hh–10), as amended by section 101,
11 is further amended—

12 (A) in paragraph (2)—

13 (i) by redesignating subparagraphs
14 (C) through (F) as subparagraphs (D)
15 through (G), respectively; and

16 (ii) by inserting after subparagraph
17 (B) the following new subparagraph:

18 “(C) the Strategic National Stockpile pur-
19 suant to section 319F–2;” and

20 (B) in paragraph (3)—

21 (i) in subparagraph (A), by adding
22 “and” at the end;

23 (ii) by striking subparagraph (B); and

24 (iii) by redesignating subparagraph
25 (C) as subparagraph (B).

1 (b) DISCLOSURES.—Subsection (d) of section 319F–
2 2 of the Public Health Service Act (42 U.S.C. 247d–6b)
3 is amended to read as follows:

4 “(d) DISCLOSURES.—No Federal agency shall dis-
5 close under section 552 of title 5, United States Code, any
6 information identifying—

7 “(1) the location at which materials in the
8 stockpile under subsection (a) are stored;

9 “(2) the contents of the stockpile under sub-
10 section (a);

11 “(3) the location of maximum containment lab-
12 oratories;

13 “(4) floor plans of laboratories supporting med-
14 ical countermeasure development;

15 “(5) security assessments of laboratories, health
16 care facilities, and State and local health care and
17 health systems;

18 “(6) medical countermeasure distribution plans;

19 “(7) identities of employees supporting medical
20 countermeasure research;

21 “(8) results of dual-use research;

22 “(9) information concerning private-sector cy-
23 bersecurity breaches and vulnerabilities related to bi-
24 ological research facilities;

1 “(10) after-action reports from emergency re-
2 sponse exercises and from actual responses; or

3 “(11) identities or locations of first respond-
4 ers.”.

5 (c) AUTHORIZATION OF APPROPRIATIONS.—Section
6 319F–2(f)(1) of the Public Health Service Act (42 U.S.C.
7 247d–6b(f)(1)) is amended by striking “\$533,800,000 for
8 each of fiscal years 2014 through 2018” and inserting
9 “\$610,000,000 for each of fiscal years 2019 through
10 2023, to remain available until expended”.

11 (d) BIOSHIELD SPECIAL RESERVE FUND.—Para-
12 graph (1) of section 319F–2(g) of the Public Health Serv-
13 ice Act (42 U.S.C. 247d–6b(g)) is amended to read as fol-
14 lows:

15 “(1) AUTHORIZATION OF APPROPRIATIONS.—In
16 addition to amounts appropriated to the special re-
17 serve fund prior to the date of the enactment of this
18 subsection, there is authorized to be appropriated,
19 for the procurement of security countermeasures
20 under subsection (c) and for carrying out section
21 319L (relating to the Biomedical Advanced Research
22 and Development Authority), \$7,100,000,000 for the
23 fiscal years 2019 through 2028. Funds authorized
24 by the preceding sentence for fiscal years 2020
25 through 2027 may be provided by advance appro-

1 priation, to be obligated at a rate of not less than
2 \$710,000,000 per year. Amounts appropriated pur-
3 suant to this paragraph are authorized to remain
4 available until expended.”.

5 **SEC. 302. BIOMEDICAL ADVANCED RESEARCH AND DEVEL-**
6 **OPMENT AUTHORITY.**

7 (a) DEFINITION OF QUALIFIED PANDEMIC OR EPI-
8 DEMIC PRODUCTS.—Section 319L(a)(5) of the Public
9 Health Service Act (42 U.S.C. 247d–7e(a)(5)) is amended
10 by inserting before the period the following: “and includes
11 a product manufactured, used, designed, developed, modi-
12 fied, licensed, or procured to diagnose, mitigate, prevent,
13 treat, or cure an infectious disease (as defined in section
14 319F–1(a)(2))”.

15 (b) TRANSACTION AUTHORITIES.—Clause (i) of sec-
16 tion 319L(c)(5)(A) of the Public Health Service Act (42
17 U.S.C. 247d–7e(c)(5)) is amended to read as follows:

18 “(i) IN GENERAL.—The Secretary
19 shall have the authority to engage in trans-
20 actions other than a contract, grant, or co-
21 operative agreement with respect to
22 projects under this section.”.

23 (c) PANDEMIC INFLUENZA PROGRAM.—Section 319L
24 of the Public Health Service Act (42 U.S.C. 247d–7e) is
25 amended—

1 (1) by redesignating subsections (d) through (f)
2 as subsections (f) through (h), respectively; and

3 (2) by inserting after subsection (c) the fol-
4 lowing new subsections:

5 “(d) PANDEMIC INFLUENZA PROGRAM.—The Sec-
6 retary, acting through the Director of BARDA, shall es-
7 tablish and implement a program that—

8 “(1) supports research and development activi-
9 ties for qualified pandemic or epidemic products (as
10 defined in section 319F–3(i)), including by devel-
11 oping innovative technologies to enhance rapid re-
12 sponse to threats relating to pandemic influenza;

13 “(2) ensures readiness to respond to pandemic
14 influenza threats by supporting the development and
15 manufacturing of influenza virus seeds, clinical trial
16 lots, and stockpiles of novel influenza strains; and

17 “(3) sustains and replenishes pandemic stock-
18 piles of bulk antigen and adjuvant material, includ-
19 ing annually testing the potency and shelf-life poten-
20 tial of all existing pandemic stockpiles held by the
21 Department of Health and Human Services.

22 “(e) EMERGING INFECTIOUS DISEASE PROGRAM.—
23 The Secretary, acting through the Director of BARDA,
24 shall establish and implement a program that supports re-
25 search and development, and manufacturing infrastruc-

1 ture, activities with respect to an emerging infectious dis-
2 ease.”.

3 (d) FUNDING.—Section 319L(e) of the Public Health
4 Service Act (42 U.S.C. 247d–7e(e)), as redesignated by
5 subsection (b)(1), is amended—

6 (1) in paragraph (2)—

7 (A) by inserting “(other than subsections
8 (d) and (e))” after “purposes of this section”;
9 and

10 (B) by striking “\$415,000,000 for each of
11 fiscal years 2014 through 2018” and inserting
12 “\$536,700,000 for each of fiscal years 2019
13 through 2023”; and

14 (2) by adding at the end the following new
15 paragraphs:

16 “(3) FUNDING FOR PANDEMIC INFLUENZA PRO-
17 GRAM.—

18 “(A) IN GENERAL.—To carry out the pur-
19 poses of subsection (d), there is authorized to
20 be appropriated \$250,000,000 for each of fiscal
21 years 2019 through 2023, to remain available
22 until expended.

23 “(B) SUPPLEMENT NOT SUPPLANT.—Any
24 funds provided to the Secretary under this
25 paragraph shall be used to supplement and not

1 supplant any other Federal funds provided to
2 carry out the purposes of subsection (d).

3 “(4) FUNDING FOR EMERGING INFECTIOUS DIS-
4 EASE PROGRAM.—To carry out the purposes of sub-
5 section (e), there is authorized to be appropriated
6 \$250,000,000 for each of fiscal years 2019 through
7 2023, to remain available until expended.”.

8 **TITLE IV—MISCELLANEOUS** 9 **PROVISIONS**

10 **SECTION 401. CYBERSECURITY.**

11 (a) NATIONAL HEALTH SECURITY STRATEGY.—Sec-
12 tion 2802(b)(7)(A) of the Public Health Service Act (42
13 U.S.C. 300hh–1) is amended by inserting after “nuclear
14 agent or agents” the following: “or cybersecurity threat”.

15 (b) COORDINATION OF PREPAREDNESS FOR AND RE-
16 SPONSE TO ALL-HAZARDS PUBLIC HEALTH EMER-
17 GENCIES.—Section 2811 of the Public Health Service Act
18 (42 U.S.C. 300hh–10), as amended by sections 101 and
19 301, is further amended—

20 (1) in subsection (c)—

21 (A) in paragraph (3)—

22 (i) in subparagraph (A), by striking
23 “and” at the end; and

24 (ii) by inserting after subparagraph

25 (B) the following:

1 “(C) the Healthcare Cybersecurity Com-
2 munications and Integration Center, or any
3 successor; and”;

4 (B) by redesignating paragraph (4) as
5 paragraph (5); and

6 (C) by inserting after paragraph (3) the
7 following:

8 “(4) have lead responsibility within the Depart-
9 ment of Health and Human Services for ensuring
10 the ability of the healthcare sector to provide con-
11 tinuity of care during a cybersecurity incident; and”;
12 and

13 (2) in subsection (d)—

14 (A) in paragraph (1), by inserting by in-
15 serting “cybersecurity,” after “radiological,”;

16 (B) in paragraph (2)(A), by inserting after
17 “nuclear agent or agents” the following: “and
18 cybersecurity threats”; and

19 (C) in paragraph (2)(C), by inserting “cy-
20 bersecurity,” after “radiological,”.

21 (c) IMPROVING STATE AND LOCAL PUBLIC HEALTH
22 SECURITY.—Section 319C–1 of the Public Health Service
23 Act (42 U.S.C. 247d-3a), as amended by section 202, is
24 further amended—

1 (1) in subsection (b)(2)(A)(i), by inserting “cyber-
2 bersecurity,” after “radiological,”; and

3 (2) in subsection (g)(1)(A), by inserting “cyber-
4 security,” after “radiological,”.

5 (d) PARTNERSHIPS FOR STATE AND REGIONAL PRE-
6 PAREDNESS TO IMPROVE SURGE CAPACITY.—Subsection
7 (c) of section 319C–2 of the Public Health Service Act
8 (42 U.S.C. 247d-3b), as amended by section 203, is fur-
9 ther amended by inserting “cybersecurity,” after “radio-
10 logical,”.

11 (e) AUTHORIZATION FOR MEDICAL PRODUCTS FOR
12 USE IN EMERGENCIES.—Section 564(b)(1)(C) of the Fed-
13 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–
14 3) is amended by inserting after “nuclear agent or agents”
15 the following: “and cybersecurity threats”.

16 (f) EMERGENCY USE OF MEDICAL PRODUCTS.—Sec-
17 tion 564A(a)(1)(B)(i) of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 360bbb–3a) is amended by in-
19 serting after “nuclear agent or agents” the following: “or
20 cybersecurity threat”.

21 (g) COUNTERMEASURE DEVELOPMENT, REVIEW,
22 AND TECHNICAL ASSISTANCE.—Section 565 of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–
24 4) is amended—

1 (1) in subsection (a)(4)(A), by inserting “cyber-
2 security,” after “radiological,”; and

3 (2) in subsection (e)(1), by inserting after
4 “posed by” the following: “cybersecurity threats or”.

5 (h) BIOMEDICAL ADVANCED RESEARCH AND DEVEL-
6 OPMENT AUTHORITY.—Section 319L(h)(2) of the Public
7 Health Service Act (42 U.S.C. 247d–7e), as redesignated
8 by section 302, is further amended—

9 (1) in subparagraph (A), by inserting “cyberse-
10 curity,” after “radiological,”; and

11 (2) in subparagraph (C)(ii), by inserting after
12 “nuclear agents” the following: “and cybersecurity
13 threats”.

14 **SEC. 402. MISCELLANEOUS FDA AMENDMENTS.**

15 (a) DRUG DEVELOPMENT TOOLS.—Section 507(c) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 357) is amended—

18 (1) by redesignating paragraph (3) as para-
19 graph (4); and

20 (2) by inserting after paragraph (2) the fol-
21 lowing:

22 “(3) NATIONAL SECURITY LIMITATION.—In
23 making information publicly available pursuant to
24 paragraph (1), the Secretary—

1 “(A) shall not disclose information that
2 would compromise national security; and

3 “(B) may make available summaries in
4 lieu of data and evidence contained in qualifica-
5 tion submissions.”.

6 (b) EMERGENCY USE INSTRUCTIONS.—Subpara-
7 graph (A) of section 564A(e)(2) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is
9 amended by striking “subsection (a)(1)(C)(i)” and insert-
10 ing “subsection (a)(1)(C)”.

11 (c) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
12 tion 564B(2) of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 360bbb–3b) is amended—

14 (1) in subparagraph (B), by inserting a comma
15 after “505”; and

16 (2) in subparagraph (C), by inserting “or sec-
17 tion 564A” before the period at the end.