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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SEC. 1. SHORT TITLE.

This Act may be cited as the “Pandemic and All-Hazards Preparedness Reauthorization Act of 2018”.

SEC. 2. TABLE OF CONTENTS.

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 procure-
ment.
Sec. 302. Biomedical advanced research and development authority.

TITLE IV—MISCELLANEOUS PROVISIONS

Sec. 401. Cybersecurity.
Sec. 402. Miscellaneous FDA amendments.
(1) in subsection (b)(4)(G), by inserting “the pandemic influenza and emerging infectious disease program established under section 319L(d), or” before “all-hazards medical and public health preparedness and response”; and

(2) in subsection (b)(7), by inserting “the research and development activities of the pandemic influenza and emerging infectious disease program established under section 319L(d) with respect to qualified pandemic or epidemic products (as defined in section 319F–3), and” before “the medical countermeasure priorities described in subsection (d)”.

SEC. 102. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

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

(1) by redesignating section 2811A as 2811B;

and

(2) by inserting after section 2811 the following:

“SEC. 2811A. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

“(a) IN GENERAL.—The Secretary shall establish and the Assistant Secretary for Preparedness and Response may convene an interagency panel of advisors to
be known as the Public Health Emergency Medical Countermeasures Enterprise (in this section referred to as the ‘PHEMCE’).

“(b) MEMBERS.—In addition to the Assistant Secretary for Preparedness and Response, who shall serve as Chair, the PHEMCE shall include the following members:

“(1) The Director of the Biomedical Advanced Research and Development Authority (or the Director’s designee).

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

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

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

“(5) The Secretary of Defense (or the Secretary’s designee).

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

“(7) The Secretary of Agriculture (or the Secretary’s designee).

“(8) The Secretary of Veterans Affairs (or the Secretary’s designee).
“(9) Representatives of any other Federal agencies, as the Assistant Secretary for Preparedness and Response determines appropriate.

“(c) FUNCTIONS.—The PHEMCE shall—

“(1) advise the Assistant Secretary for Preparedness and Response regarding research, development, and procurement of security countermeasures (as defined in section 319F–2(c)) based on the health security needs of the United States; and

“(2) assist the Assistant Secretary for Preparedness and Response in the identification of gaps in public health preparedness and response related to such security countermeasures and challenges to addressing such needs (including any regulatory challenges).”.

SEC. 103. NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS.

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

SEC. 104. NATIONAL DISASTER MEDICAL SYSTEM PERSONNEL.

(a) Direct Hire Authority.—Section 2812(c)(1) of the Public Health Service Act (42 U.S.C. 300hh–
11(c)(1)) is amended by striking “in accordance with applicable civil service laws and regulations” and inserting “without regard to those provisions of title 5, United States Code, governing appointments in the competitive service”.

(b) Death Benefits.—Section 1204(9) of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10284(9)) is amended—

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

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

(3) by adding at the end the following:

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

(c) Authorization of Appropriations.—Section 2812(g) of the Public Health Service Act (42 U.S.C. 300hh–11(g)) is amended by striking “$52,700,000 for each of fiscal years 2014 through 2018” and inserting “$57,400,000 for each of fiscal years 2019 through 2023”.
SEC. 105. VOLUNTEER MEDICAL RESERVE CORPS.

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

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

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

SEC. 106. CONTINUING THE ROLE OF THE DEPARTMENT OF VETERANS AFFAIRS.

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

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

SEC. 201. PUBLIC HEALTH EMERGENCIES.

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

(1) by amending subsection (b) to read as follows:

“(b) PUBLIC HEALTH EMERGENCY RESPONSE FUND.—
“(1) Establishment.—There is established in the Treasury a fund to be designated as the ‘Public Health Emergency Response Fund’ (referred to in this subsection as the ‘Fund’) to be made available to the Secretary for the following purposes:

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

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

“(i) to occur; and

“(ii) to affect national security or the health and security of United States citizens domestically or internationally.

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

“(i) a chemical, biological, radiological, or nuclear threat; or

“(ii) an emerging infectious disease.

“(D) To develop and procure medical countermeasures for a chemical, biological, radiological, or nuclear threat, or an emerging infectious disease.
“(2) FUNDING.—The Secretary may transfer to the Fund such amounts as are necessary from any discretionary appropriations (pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) made available in any appropriations Act, provided that no such appropriation is reduced by more than 1 percent. Any such transferred amounts shall remain available until expended.

“(3) TRANSFER OF FUNDS TO OTHER ACCOUNTS.—The Secretary may transfer amounts in the Fund to other accounts in the Department of Health and Human Services for the purposes described in paragraph (1).

“(4) SUPPLEMENT NOT SUPPLANT.—

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

“(B) TRANSFER AUTHORITIES.—The transfer authority under this section is in addition to any other transfer authority otherwise available to the Secretary.

“(5) STRATEGIC NATIONAL STOCKPILE.—Any product purchased using amounts in the Fund may, at the discretion of the Secretary, be maintained in
the Strategic National Stockpile under section 319F–2.

“(6) REPORT.—Not later than 90 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report describing—

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

“(B) each public health emergency for which expenditures were made and the activities undertaken with respect to each such emergency; and

“(C) any unobligated balances in the Fund and all obligations incurred for such fiscal year, including obligations by program, project, or activity.”;

(2) by striking subsection (c); and

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

(b) TEMPORARY REASSIGNMENT OF FEDERALLY FUNDED PERSONNEL.—Subsection (d)(8) of section 319
of the Public Health Service Act (42 U.S.C. 247d), as re-
designated by subsection (a)(3), is amended by striking
“2018” and inserting “2023”.

SEC. 202. IMPROVING STATE AND LOCAL PUBLIC HEALTH
SECURITY.

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

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

(a) IN GENERAL.—Section 319C–2 of the Public
Health Service Act (42 U.S.C. 247d–3b) is amended—
(1) in the section heading, by striking “HOS-
PITAL PREPAREDNESS” and inserting “HOS-
PITAL PREPAREDNESS AND RESPONSE”; and
(2) by amending subsection (a) to read as fol-
lows:
“(a) In General.—The Secretary shall award competitive grants or cooperative agreements to eligible entities to enable such entities—

“(1) to improve surge capacity and enhance community and hospital preparedness for public health emergencies, including, as appropriate, capacity and preparedness to address the needs of children and other at-risk individuals; and

“(2) to implement response activities, including a medical surge, in the event of such an emergency.”.

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

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

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

(3) by adding at the end the following:

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

(c) Authorization of Appropriations.—Subsection (j) of section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b(j)) is amended in paragraph (1), by striking “$374,700,000 for each of fiscal years 2014
SEC. 204. REVITALIZING THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

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

SEC. 205. AUTHORIZATION OF APPROPRIATIONS FOR EMERGENCY SYSTEM FOR ADVANCED REGISTRATION OF VOLUNTEER HEALTH PROFESSIONALS.

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

TITLE III—ACCELERATING MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

SEC. 301. STRATEGIC NATIONAL STOCKPILE AND SECURITY COUNTERMEASURE PROCUREMENT.

(a) IN GENERAL.—
(1) DELEGATION TO ASPR.—Subsection (a)(1) of section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended by striking “in collaboration with the Director of the Centers for Disease Control and Prevention” and inserting “acting through the Assistant Secretary for Preparedness and Response”.

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

(A) in paragraph (2)—

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

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

“(C) the Strategic National Stockpile pursuant to section 319F–2;”; and

(B) in paragraph (3)—

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

(ii) by striking subparagraph (B); and

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

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

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

“(2) the contents of the stockpile under subsection (a);

“(3) the location of maximum containment laboratories;

“(4) floor plans of laboratories supporting medical countermeasure development;

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

“(6) medical countermeasure distribution plans;

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

“(8) results of dual-use research;

“(9) information concerning private-sector cybersecurity breaches and vulnerabilities related to biological research facilities;
“(10) after-action reports from emergency response exercises and from actual responses; or

“(11) identities or locations of first responders.”.

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

(d) BIOSHIELD SPECIAL RESERVE FUND.—Paragraph (1) of section 319F–2(g) of the Public Health Service Act (42 U.S.C. 247d–6b(g)) is amended to read as follows:

“(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts appropriated to the special reserve fund prior to the date of the enactment of this subsection, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 319L (relating to the Biomedical Advanced Research and Development Authority), $7,100,000,000 for the fiscal years 2019 through 2028. Funds authorized by the preceding sentence for fiscal years 2020 through 2027 may be provided by advance appro-
priation, to be obligated at a rate of not less than $710,000,000 per year. Amounts appropriated pursuant to this paragraph are authorized to remain available until expended.”.

SEC. 302. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

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

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

“(i) IN GENERAL.—The Secretary shall have the authority to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects under this section.”.

(e) PANDEMIC INFLUENZA PROGRAM.—Section 319L of the Public Health Service Act (42 U.S.C. 247d–7e) is amended—
(1) by redesignating subsections (d) through (f) as subsections (f) through (h), respectively; and

(2) by inserting after subsection (c) the following new subsections:

“(d) PANDEMIC INFLuenza Program.—The Secretary, acting through the Director of BARDA, shall establish and implement a program that—

“(1) supports research and development activities for qualified pandemic or epidemic products (as defined in section 319F–3(i)), including by developing innovative technologies to enhance rapid response to threats relating to pandemic influenza;

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

“(3) sustains and replenishes pandemic stockpiles of bulk antigen and adjuvant material, including annually testing the potency and shelf-life potential of all existing pandemic stockpiles held by the Department of Health and Human Services.

“(e) EMERGING INFECTIOUS Disease Program.—The Secretary, acting through the Director of BARDA, shall establish and implement a program that supports research and development, and manufacturing infrastruc-
ture, activities with respect to an emerging infectious disease.”.

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

(1) in paragraph (2)—

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

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

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

“(3) FUNDING FOR PANDEMIC INFLUENZA PROGRAM.—

“(A) IN GENERAL.—To carry out the purposes of subsection (d), there is authorized to be appropriated $250,000,000 for each of fiscal years 2019 through 2023, to remain available until expended.

“(B) SUPPLEMENT NOT SUPPLANT.—Any funds provided to the Secretary under this paragraph shall be used to supplement and not
supplant any other Federal funds provided to carry out the purposes of subsection (d).

“(4) FUNDING FOR EMERGING INFECTIOUS DISEASE PROGRAM.—To carry out the purposes of subsection (e), there is authorized to be appropriated $250,000,000 for each of fiscal years 2019 through 2023, to remain available until expended.”.

TITLE IV—MISCELLANEOUS PROVISIONS

SECTION 401. CYBERSECURITY.

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

(b) COORDINATION OF PREPAREDNESS FOR AND RESPONSE TO ALL-HAZARDS PUBLIC HEALTH EMERGENCIES.—Section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10), as amended by sections 101 and 301, is further amended—

(1) in subsection (c)—

(A) in paragraph (3)—

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

(ii) by inserting after subparagraph (B) the following:
“(C) the Healthcare Cybersecurity Communications and Integration Center, or any successor; and”;

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

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

“(4) have lead responsibility within the Department of Health and Human Services for ensuring the ability of the healthcare sector to provide continuity of care during a cybersecurity incident; and”;

and

(2) in subsection (d)—

(A) in paragraph (1), by inserting by inserting “cybersecurity,” after “radiological,”;

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

(C) in paragraph (2)(C), by inserting “cybersecurity,” after “radiological,”.

(c) IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.—Section 319C–1 of the Public Health Service Act (42 U.S.C. 247d-3a), as amended by section 202, is further amended—
(1) in subsection (b)(2)(A)(i), by inserting “cybersecurity,” after “radiological,”; and

(2) in subsection (g)(1)(A), by inserting “cybersecurity,” after “radiological,”.

(d) PARTNERSHIPS FOR STATE AND REGIONAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—Subsection (c) of section 319C–2 of the Public Health Service Act (42 U.S.C. 247d-3b), as amended by section 203, is further amended by inserting “cybersecurity,” after “radiological,”.

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

(f) EMERGENCY USE OF MEDICAL PRODUCTS.—Section 564A(a)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a) is amended by inserting after “nuclear agent or agents” the following: “or cybersecurity threat”.

(g) COUNTERMEASURE DEVELOPMENT, REVIEW, AND TECHNICAL ASSISTANCE.—Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amended—
(1) in subsection (a)(4)(A), by inserting “cybersecurity,” after “radiological,”; and

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

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

(1) in subparagraph (A), by inserting “cybersecurity,” after “radiological,”; and

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

SEC. 402. MISCELLANEOUS FDA AMENDMENTS.

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

(1) by redesignating paragraph (3) as paragraph (4); and

(2) by inserting after paragraph (2) the following:

“(3) NATIONAL SECURITY LIMITATION.—In making information publicly available pursuant to paragraph (1), the Secretary—
“(A) shall not disclose information that would compromise national security; and

“(B) may make available summaries in lieu of data and evidence contained in qualification submissions.”.

(b) EMERGENCY USE INSTRUCTIONS.—Subparagraph (A) of section 564A(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is amended by striking “subsection (a)(1)(C)(i)” and inserting “subsection (a)(1)(C)”.

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

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

(2) in subparagraph (C), by inserting “or section 564A” before the period at the end.