

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 2405
OFFERED BY M . _____**

Page 4, line 3, insert “, to the extent practicable,”
after “meeting”.

Page 4, line 4, strike “to the degree practicable”.

Page 5, line 11, strike “such”.

Page 5, line 14, amend paragraph (1) to read as follows:

1 (1) CONTRACT TERMS.—Subclause (IX) of sec-
2 tion 319F-2(c)(7)(C)(ii) of the Public Health Serv-
3 ice Act (42 U.S.C. 247d-6b(c)(7)(C)(ii)) is amended
4 to read as follows:

5 “(IX) CONTRACT TERMS.—The
6 Secretary, in any contract for procure-
7 ment under this section—

8 “(aa) may specify—

9 “(AA) the dosing and
10 administration requirements
11 for countermeasures to be
12 developed and procured;

1 “(BB) the amount of
2 funding that will be dedi-
3 cated by the Secretary for
4 development and acquisition
5 of the countermeasure; and

6 “(CC) the specifications
7 the countermeasure must
8 meet to qualify for procure-
9 ment under a contract under
10 this section; and

11 “(bb) shall provide a clear
12 statement of defined Government
13 purpose limited to uses related to
14 a security countermeasure, as de-
15 fined in paragraph (1)(B).”.

Page 7, line 6, strike “the relevant committees of Congress” and insert “the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate”.

Page 8, line 16, strike “HEALTH PROFESSIONS VOLUNTEERS” and insert “VOLUNTEER HEALTH PROFESSIONALS”.

Page 11, line 22, strike “Coordinated” and insert “Fatality management, and coordinated”.

Page 11, line 25, strike “, and fatality management”.

Page 13, line 21, strike “consider factors including each of the following” and insert “consider each of the following”.

Page 13, strike lines 23 through 25 and insert the following:

1 “(i) The degree to which the emer-
2 gency cannot be adequately and appro-
3 priately addressed by the public health
4 workforce.

Page 14, line 2, insert “or would otherwise benefit from” after “requires”.

Page 14, line 3, strike “non-preparedness” and insert “nonpreparedness”.

Page 15, line 3, strike “but only if” and all that follows through “such an extension.” and insert the following: “but only if—

 “(I) the extension is requested by
 the entity that requested authority to

authorize a temporary redeployment;
and

1 “(II) the Secretary gives notice
2 to the Congress in conjunction with
3 the extension.”.

Page 16, line 10, insert “to such activities” after
“challenges”.

Page 16, line 18, strike “ability” and insert “activi-
ties”.

Page 16, line 20, strike “by” and insert “the”.

Page 16, line 21, strike “coordinating the” and in-
sert “coordination of relevant”.

Page 17, line 1, strike “establishing” and insert “es-
tablishment of”.

Page 17, after line 7, insert the following (and re-
designate the subsequent paragraphs accordingly):

4 “(1) have lead responsibility within the Depart-
5 ment of Health and Human Services for emergency
6 preparedness and response policy and coordination;

Page 17, line 18, insert “and” after the semicolon.

Page 17, lines 19 and 20, strike subparagraph (D).

Page 18, line 2, strike “and” after the semicolon.

Page 18, after line 3, insert the following:

1 “(C) the Medical Reserve Corps pursuant
2 to section 2813; and

Page 18, line 11, strike “relevant congressional committees” and insert “the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate”.

Page 19, strike lines 5 through 9 and insert the following: “procurement awards, including—

 “(A) the time elapsed from the issuance of the initial solicitation or request for a proposal to the adjudication (such as the award, denial of award, or solicitation termination);”.

Page 19, line 10, redesignate subparagraph (A) as subparagraph (B).

Page 19, line 13, redesignate subparagraph (B) as subparagraph (C).

Page 19, line 14, insert “such” after “each”.

Page 19, line 19, redesignate subparagraph (C) as subparagraph (D).

Page 19, line 23, strike “paragraph (4)” and insert “paragraph (4)(C)”.

Page 21, line 4, insert “of the Nation” after “vulnerabilities”.

Page 21, line 18, strike “relevant congressional committees” and insert “the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate”.

After section 5, insert the following (and redesignate section 6 as section 9):

1 **SEC. 6. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
2 **USE IN EMERGENCIES.**

3 Section 564 of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 360bbb–3) is amended—

5 (1) in subsection (a)—

6 (A) in paragraph (1), by striking “sections
7 505, 510(k), and 515 of this Act” and inserting
8 “any provision of this Act”;

9 (B) in paragraph (2)(A), by striking
10 “under a provision of law referred to in such
11 paragraph” and inserting “under a provision of
12 law in section 505, 510(k), or 515 of this Act

1 or section 351 of the Public Health Service
2 Act”; and

3 (C) in paragraph (3), by striking “a provi-
4 sion of law referred to in such paragraph” and
5 inserting “a provision of law referred to in
6 paragraph (2)(A)”;

7 (2) in subsection (b)—

8 (A) in the subsection heading, by striking
9 “DECLARATION OF EMERGENCY” and inserting
10 “DECLARATION SUPPORTING EMERGENCY USE
11 AUTHORIZATION”;

12 (B) in paragraph (1)—

13 (i) in the matter preceding subpara-
14 graph (A), by striking “an emergency jus-
15 tifying” and inserting “that circumstances
16 exist justifying”;

17 (ii) in subparagraph (A), by striking
18 “specified”;

19 (iii) in subparagraph (B), by striking
20 “specified”; and

21 (iv) by amending subparagraph (C) to
22 read as follows:

23 “(C) a determination by the Secretary that
24 there is a public health emergency, or a signifi-
25 cant potential for a public health emergency, in-

1 volving a heightened risk to national security or
2 the health and security of United States citi-
3 zens abroad, and involving a biological, chem-
4 ical, radiological, or nuclear agent or agents, or
5 a disease or condition that may be attributable
6 to such agent or agents.”;

7 (C) in paragraph (2)—

8 (i) by amending subparagraph (A) to
9 read as follows:

10 “(A) IN GENERAL.—A declaration under
11 this subsection shall terminate upon a deter-
12 mination by the Secretary, in consultation with,
13 as appropriate, the Secretary of Homeland Se-
14 curity or the Secretary of Defense, that the cir-
15 cumstances described in paragraph (1) have
16 ceased to exist.”;

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

18 (iii) by redesignating subparagraph

19 (C) as subparagraph (B); and

20 (D) in paragraph (4), by striking “advance
21 notice of termination, and renewal” and insert-
22 ing “and advance notice of termination”;

23 (3) in subsection (c)(1), by striking “specified
24 in” and insert “covered by”;

1 (4) in subsection (d)(3), by inserting “, to the
2 extent practicable given the circumstances of the
3 emergency,” after “including”;

4 (5) in subsection (e)—

5 (A) in paragraph (1)(B), by amending
6 clause (iii) to read as follows:

7 “(iii) Appropriate conditions with re-
8 spect to the collection and analysis of in-
9 formation concerning the safety and effec-
10 tiveness of the product with respect to the
11 actual use of such product pursuant to an
12 authorization under this section.”;

13 (B) in paragraph (2)—

14 (i) in subparagraph (A)—

15 (I) by striking “manufacturer of
16 the product” and inserting “person”;
17 and

18 (II) by inserting “or in para-
19 graph (1)(B)” before the period at the
20 end;

21 (ii) in subparagraph (B)(i), by insert-
22 ing “, with the exception of extensions of
23 a product’s expiration date authorized
24 under section 564A(b)” before the period
25 at the end; and

1 (iii) by amending subparagraph (C) to
2 read as follows:

3 “(C) In establishing conditions under this
4 paragraph with respect to the distribution and
5 administration of a product, the Secretary shall
6 not impose conditions that would restrict dis-
7 tribution or administration of the product that
8 is solely for the approved uses.”;

9 (C) by amending paragraph (3) to read as
10 follows:

11 “(3) GOOD MANUFACTURING PRACTICE; PRE-
12 SCRIPTON; PRACTITIONER’S AUTHORIZATION.—With
13 respect to the emergency use of a product for which
14 an authorization under this section is issued (wheth-
15 er for an unapproved product or an unapproved use
16 of an approved product), the Secretary may waive or
17 limit, to the extent appropriate given the cir-
18 cumstances of the emergency—

19 “(A) requirements regarding current good
20 manufacturing practice otherwise applicable to
21 the manufacture, processing, packing, or hold-
22 ing of products subject to regulation under this
23 Act, including such requirements established
24 under section 501 or 520(f)(1), and including
25 relevant conditions prescribed with respect to

1 the product by an order under section
2 520(f)(2);

3 “(B) requirements established under sec-
4 tion 503(b); and

5 “(C) requirements established under sec-
6 tion 520(e).”; and

7 (D) by adding at the end the following:

8 “(5) EXISTING AUTHORITIES.—Nothing in this
9 section restricts any authority vested in the Sec-
10 retary by any other provision of this Act or the Pub-
11 lic Health Service Act for establishing conditions of
12 authorization for a product.”; and

13 (6) in subsection (g)—

14 (A) in the heading, by striking “REVOCA-
15 TION OF AUTHORIZATION” and inserting “RE-
16 VIEW, MODIFICATION, AND REVOCATION OF
17 AUTHORIZATION”;

18 (B) in paragraph (1), by striking “periodi-
19 cally review” and inserting “review not less
20 than every three years”; and

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

22 “(3) MODIFICATION.—The Secretary may mod-
23 ify an authorization under this section or the condi-
24 tions of such an authorization, at any time, based on
25 a review of the authorization or new information

1 that is otherwise obtained, including information ob-
2 tained during an emergency.”.

3 **SEC. 7. ADDITIONAL PROVISIONS RELATED TO MEDICAL**
4 **PRODUCTS FOR EMERGENCY USE.**

5 (a) IN GENERAL.—The Federal Food, Drug, and
6 Cosmetic Act is amended by inserting after section 564
7 (21 U.S.C. 360bbb–3) the following:

8 **“SEC. 564A. ADDITIONAL PROVISIONS RELATED TO MED-**
9 **ICAL PRODUCTS FOR EMERGENCY USE.**

10 “(a) DEFINITIONS.—For purposes of this section:

11 “(1) The term ‘product’ means a drug, device,
12 or biological product.

13 “(2) The term ‘eligible product’ means a prod-
14 uct that is—

15 “(A) approved or cleared under this chap-
16 ter or licensed under section 351 of the Public
17 Health Service Act; and

18 “(B) intended to be used to diagnose, pre-
19 vent, or treat a disease or condition involving a
20 biological, chemical, radiological, or nuclear
21 agent or agents during—

22 “(i) a domestic emergency or military
23 emergency involving heightened risk of at-
24 tack with such an agent or agents; or

1 “(ii) a public health emergency affect-
2 ing national security or the health and se-
3 curity of United States citizens abroad.

4 “(b) EXPIRATION DATING.—

5 “(1) IN GENERAL.—The Secretary may extend
6 the expiration date and authorize the introduction or
7 delivery for introduction into interstate commerce of
8 an eligible product after the expiration date provided
9 by the manufacturer if—

10 “(A) the eligible product is intended to be
11 held for use for a domestic, military, or public
12 health emergency described in subsection
13 (a)(2)(B);

14 “(B) the expiration date extension is in-
15 tended to support the United States’ ability to
16 protect—

17 “(i) the public health; or

18 “(ii) military preparedness and effec-
19 tiveness; and

20 “(C) the expiration date extension is sup-
21 ported by an appropriate scientific evaluation
22 that is conducted or accepted by the Secretary.

23 “(2) REQUIREMENTS AND CONDITIONS.—Any
24 extension of an expiration date under paragraph (1)
25 shall, as part of the extension, identify—

1 “(A) each specific lot, batch, or other unit
2 of the product for which extended expiration is
3 authorized;

4 “(B) the duration of the extension; and

5 “(C) any other requirements or conditions
6 as the Secretary may deem appropriate for the
7 protection of the public health, which may in-
8 clude requirements for, or conditions on, prod-
9 uct sampling, storage, packaging or repack-
10 aging, transport, labeling, notice to product re-
11 cipients, recordkeeping, periodic testing or re-
12 testing, or product disposition.

13 “(3) EFFECT.—Notwithstanding any other pro-
14 vision of this Act or the Public Health Service Act,
15 an eligible product shall not be considered an unap-
16 proved product (as defined in section 564(a)(2)(A))
17 and shall not be deemed adulterated or misbranded
18 under this Act because, with respect to such prod-
19 uct, the Secretary has, under paragraph (1), ex-
20 tended the expiration date and authorized the intro-
21 duction or delivery for introduction into interstate
22 commerce of such product after the expiration date
23 provided by the manufacturer.

24 “(c) CURRENT GOOD MANUFACTURING PRAC-
25 TICES.—

1 “(1) IN GENERAL.—The Secretary may, when
2 the circumstances of a domestic, military, or public
3 health emergency described in subsection (a)(2)(B)
4 so warrant, authorize, with respect to an eligible
5 product, deviations from current good manufac-
6 turing practice requirements otherwise applicable to
7 the manufacture, processing, packing, or holding of
8 products subject to regulation under this Act, in-
9 cluding requirements under section 501 or 520(f)(1)
10 or applicable conditions prescribed with respect to
11 the eligible product by an order under section
12 520(f)(2).

13 “(2) EFFECT.—Notwithstanding any other pro-
14 vision of this Act or the Public Health Service Act,
15 an eligible product shall not be considered an unap-
16 proved product (as defined in section 564(a)(2)(A))
17 and shall not be deemed adulterated or misbranded
18 under this Act because, with respect to such prod-
19 uct, the Secretary has authorized deviations from
20 current good manufacturing practices under para-
21 graph (1).

22 “(d) MASS DISPENSING.—The requirements of sec-
23 tion 503(b) and 520(e) shall not apply to an eligible prod-
24 uct, and the product shall not be considered an unap-
25 proved product (as defined in section 564(a)(2)(A)) and

1 shall not be deemed adulterated or misbranded under this
2 Act because it is dispensed without an individual prescrip-
3 tion, if—

4 “(1) the product is dispensed during an actual
5 emergency described in subsection (a)(2)(B); and

6 “(2) such dispensing without an individual pre-
7 scription occurs—

8 “(A) as permitted under the law of the
9 State in which the product is dispensed; or

10 “(B) in accordance with an order issued by
11 the Secretary.

12 “(e) EMERGENCY USE INSTRUCTIONS.—

13 “(1) IN GENERAL.—The Secretary, acting
14 through an appropriate official within the Depart-
15 ment of Health and Human Services, may create
16 and issue emergency use instructions to inform
17 health care providers or individuals to whom an eli-
18 gible product is to be administered concerning such
19 product’s approved, licensed, or cleared conditions of
20 use.

21 “(2) EFFECT.—Notwithstanding any other pro-
22 visions of this Act or the Public Health Service Act,
23 a product shall not be considered an unapproved
24 product (as defined in section 564(a)(2)(A)) and

1 shall not be deemed adulterated or misbranded
2 under this Act because of—

3 “(A) the issuance of emergency use in-
4 structions under paragraph (1) with respect to
5 such product; or

6 “(B) the introduction or delivery for intro-
7 duction of such product into interstate com-
8 merce accompanied by such instructions during
9 an emergency response to an actual emergency
10 described in subsection (a)(2)(B).”.

11 (b) RISK EVALUATION AND MITIGATION STRATE-
12 GIES.—Section 505–1 of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 355-1), is amended—

14 (1) in subsection (f), by striking paragraph (7);

15 and

16 (2) by adding at the end the following:

17 “(k) WAIVER IN PUBLIC HEALTH EMERGENCIES.—

18 The Secretary may waive any requirement of this section
19 with respect to a qualified countermeasure (as defined in
20 section 319F–1(a)(2) of the Public Health Service Act)
21 to which a requirement under this section has been ap-
22 plied, if the Secretary determines that such waiver is re-
23 quired to mitigate the effects of, or reduce the severity
24 of, an actual or potential domestic emergency or military
25 emergency involving heightened risk of attack with a bio-

1 logical, chemical, radiological, or nuclear agent, or an ac-
2 tual or potential public health emergency affecting na-
3 tional security or the health and security of United States
4 citizens abroad.”.

5 **SEC. 8. PRODUCTS HELD FOR EMERGENCY USE.**

6 The Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 301 et seq.) is amended by inserting after section
8 564A, as added by section 7, the following:

9 **“SEC. 564B. PRODUCTS HELD FOR EMERGENCY USE.**

10 “It is not a violation of any section of this Act or
11 of the Public Health Service Act for a government entity
12 (including a Federal, State, local, and tribal government
13 entity), or a person acting on behalf of such a government
14 entity, to introduce into interstate commerce a product (as
15 defined in section 564(a)(4)) intended for emergency use,
16 if that product—

17 “(1) is intended to be held and not used; and

18 “(2) is held and not used, unless and until that
19 product—

20 “(A) is approved, cleared, or licensed
21 under section 505, 510(k), or 515 of this Act
22 or section 351 of the Public Health Service Act;

23 “(B) is authorized for investigational use
24 under section 505 or 520 of this Act or section
25 351 of the Public Health Service Act; or

1 “(C) is authorized for use under section
2 564.”.

Page 22, line 18, insert “that the Secretary determines to be a priority” before the period.

Page 23, line 10, strike “Practice” and insert “Practices”.

Page 24, line 11, insert “, in accordance with subsection (b)(2),” after “and”.

Page 24, beginning on line 12, strike “as requested” and all that follows through “Secretary”.

Page 25, line 17, insert “such” after “no”.

Page 29, line 1, strike “relevant congressional committees” and insert “the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate”.

Page 29, line 4, strike “2012” and insert “2013”.

Page 30, line 14, strike “any other measure” and insert “a description of other measures”.

Page 30, line 15, strike “is” and insert “are”.

Page 30, line 18, insert “that relate to counter-measures or products referred to in subsection (a) and” after “priorities”.

