

AMENDMENTS ADOPTED TO THE
AGRICULTURE APPROPRIATIONS BILL
FOR FY 2017

Full Committee Markup
House Appropriations Committee
April 19, 2016

Managers' Amendment to the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017

In the bill:

Page 92, Line 6 and Line 7, strike “— (1)”; Page 92, Line 7, insert “via prior approval supplement” in between “advance” and “on”; Page 92, Line 8, insert “(1)” between “to” and “the”; Page 92, Line 12 through Line 13, strike “or an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k))”; Page 92, Line 14 through Line 16, strike “requires an identical change to be made on the same timetable to— (A)”; Page 92, Line 22 through Line 25, strike “drug; or (B) the safety information in the labeling of the reference product (as such term is used in section 351(i) of the Public Health Service”; Page 93, Line 1 through Line 4, strike “Act (42 U.S.C. 262(i)) and any other drug that is marketed pursuant to an application under section 351(k) of such Act (42 U.S.C. 262(k)) citing the same reference product”.

Page 94, Line 23, after the semicolon insert, “ “Rural Business – Cooperative Service – Rural Economic Development Loans Program Account”;

At the end of the bill (before the spending reduction account), insert the following:

“SEC. ____ . None of the funds made available by this Act may be used to write, prepare, propose, or publish a proposed rule, a final rule, or an interim final rule in furtherance of, or otherwise to implement any regulations or other regulatory requirements or policies with respect to the importation into the United States of lemons from Argentina unless and until—

(1) the Secretary of Agriculture submits to the Committee on Agriculture and the Committee on Appropriations of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry and the Committee on Appropriations of the Senate a certification that the Secretary—

(A) has completed site visits of production areas of lemons in Argentina; and

(B) has conducted pest and disease risk assessments with respect to such lemons; and

(2) the Administrator of the Office of Information and Regulatory Affairs of the Office Management and Budget submits to such Committees a certification that the Administrator has completed the assessments specified in section 6(a)(3)(C) of Executive Order 12866.”

In the report:

Page 9, under the “U.S.-Mexico Cooperation” header, add at the end:

“In addition, the Secretary shall work with his Mexican counterpart to develop a program for U.S.-Mexico academic exchanges for students in agriculture related fields of study and professional agriculture specialists. The Secretary shall brief the Committee within 180 days of the date of enactment on efforts in these areas.”

Page 10 – Before the header “EXECUTIVE OPERATIONS”, insert the following:

*“USDA and EPA Cooperation.—*Interagency Consultations.—The Department has a robust history of collecting and analyzing data related to agricultural economics and the environmental impact of farming practices upon the environment, including crop protection and pest management. Although several provisions in the Federal Insecticide, Fungicide, and Rodenticide Act require USDA and US EPA to consult and coordinate together, there has been a recent notable disconnect. Given the Department’s expertise, the Committee directs the Secretary to ensure USDA experts consult with the US EPA on regulatory decisions impacting America’s farmers.”

Page 33 – Before the header “Organic Integrity,” insert at the end of the paragraph the following:

“The Committee notes the Department has the authority to include state organic program fees and transitional certification fees when administering the program under 7 U.S.C. 6523.”

Page 34 – Before the header “Research and Promotion Programs,” insert the following:

*“Organic Rulemaking.—*The Committee is aware that USDA released a proposed rule on April 7, 2016, titled “National Organic Program: Organic Livestock and Poultry Practices.” The Committee is concerned about the potential disruption to existing organic producers and their supply chains, as well as ensuring that animal health is fully protected. Before finalizing this regulation, the Committee directs USDA to conduct an additional, thorough assessment on the costs of compliance and alternatives for existing organic producers so that producers and supply chains directly impacted by the change in rules will be minimally impacted.”

Page 37 – Before the header “Water Conserving Technologies”, insert the following:

Siluriformes Inspection Report.— Within 120 days of enactment, the Secretary shall report to the Committee the status of the implementation of the mandatory inspection program for siluriformes and catfish products. The report shall contain the dates of domestic public and technical meetings held to explain the new program and their locations; the dates of foreign technical meetings held to explain the new program and their locations; domestic catfish slaughter and processing facilities visited by inspection personnel broken down by state and the types of regulatory actions taken, if any; the names countries that notified the Department by March 1 of their intention to continue to export siluriformes to the U.S. and the number of establishments that would be eligible to export; the names of countries that notified the Department after March 1 of their intention to continue to export siluriformes to the U.S. and the number of establishments that would be eligible to export; the number of pounds of siluriformes imported beginning on April 15, 2016 broken down by country; the number of pounds that were subject to TOIs broken down by country; the specific TOIs performed broken down by country; the number of chemical and microbiological samples taken by country; the types and numbers of regulatory violations found by country. The Secretary shall also report the number of field inspection personnel assigned to the domestic facilities and the number of field inspection personnel assigned to perform import inspection.

Page 41 – Under the Risk Management Agency, after the last paragraph, insert:

“Crop Insurance in Drought Areas.— The Committee encourages the Secretary to be flexible in administering the Federal Crop Insurance program in areas impacted by natural disasters, including in drought-affected areas.”

Page 46 – Before the header “Rural Definition,” insert the following:

“Section 514 Loan Program. – The Farm Labor Housing program (Section 514) has been successful in assisting in the development of farm housing. The program presently only permits housing of certain farm workers and has not taken into consideration changes in the agricultural labor market. As a result, farmers are restricted on who can use the housing built with these funds to house the workers they need to prune and harvest their crops. USDA is directed to report to the Committees on Appropriations of the House and Senate within 90 days of enactment of this Act regarding the feasibility and impacts of amending the program to expand the list of eligible tenants permitted to live in existing housing.”

Page 50 – Under the Rural Economic Development Loans Program Account, after the last paragraph insert the following:

“Review and Selection Process. – The Committee recognizes demand for the Rural Economic Development Loan and Grant Program remains high. The Committee encourages the Rural Business-Cooperative Service to award funds on a first-come first-serve basis, after taking all other eligibility requirements into account, and not the prioritization system utilized in fiscal year 2016. The Committee supports utilizing a first-come first-serve award system as the most expeditious means to award funds to eligible projects.”

Page 57 – Before “SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM”, insert

“WIC Eligibility of Multivitamins.— The Committee encourages FNS to prepare a report assessing the inclusion of vitamins eligible for purchase as part of the supplemental foods under the special supplemental nutrition program for women, infants, and children (WIC). Such report shall include: whether there are dietary deficiencies within the WIC population that could be enhanced through such inclusion; considerations regarding the implementation and possible health impacts of such inclusion; cost considerations related to such inclusion. This report shall be submitted to the Committee not later than 90 days after enactment of this Act.”

“Zika Outreach and Education. – The Committee is supportive of ensuring pregnant women are educated on the various methods for preventing exposure to the Zika virus during pregnancy. The Committee directs the Department, in consultation with the Centers for Disease Control and Prevention, to continue its education and outreach efforts through the WIC program to provide pregnant women with the information they need to prevent Zika. During fiscal year 2017, the Department is directed to designate \$10,000,000 to assist with Zika outreach and education, with priority given to States with the greatest need.”

Page 65 – Before the header “Centers of Excellence”, insert the following:

“Blood Donor Policies.”—The Committee commends the FDA on updating their blood donor policy in the December 2015 Guidance to Industry from a lifetime ban to a one year deferral, however it continues to encourage a permanent policy change based on scientifically supported risk factors and not time passed. The Committee remains concerned that certain questions on the FDA blood donor questionnaire are outdated and discriminatory. This questionnaire should not ask about sexual orientation, rather it should assess risk factors that might expose a potential blood donor to blood-borne illness. The Committee encourages FDA to find an adequate replacement question for the blood donor questionnaire that is cognitively appropriate and will maintain a safe donor pool without discrimination.”

Page 66 – Before the header “Drug Compounding,” insert the following:

“Date Labels on Food.”—The Committee is concerned by the amount of food waste resulting from consumer confusion around date labels on food. The Committee notes that there is currently no federal uniform system for food date labels, which are currently determined by the food company to indicate quality rather than the safety of the food. The Committee urges FDA to study current and potential date labeling language and formats to determine what language and/or format is most effective in reducing consumer confusion and communicate such voluntary options to food producers.”

Page 66 – Strike the paragraph with the header “Drug Compounding” and replace with the following:

“Drug Compounding.”—The Committee believes patient access to the right drug at the right time is of utmost importance. In instances where a commercially manufactured drug is not appropriate for a patient for a specific reason, a compounded drug may be the difference between life and death. Since passage of the Drug Quality and Security Act (DQSA) of 2013, the Committee has had concerns that the FDA interpreted provisions of Section 503A of the FDCA in a manner that might jeopardize the availability of compounded medications for “office use”. The practice of “office use” occurs when a compounder will compound a batch of drugs in anticipation of receiving patient-specific prescriptions at a later time. It may also be the case of a doctor in his or her office maintaining compounded drugs on site because it is unsafe or impractical to issue a traditional prescription. This practice is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee is aware that on April 15, 2016, FDA released a new Draft Guidance on the issue of “office-use” compounding. The Committee directs the FDA to issue a Final Guidance that provides for “office-use” compounding of drugs, in appropriate circumstances as well as including drugs compounded in anticipation of a prescription for an identified individual patient. Such “anticipatory” compounded drugs must be based on the history of previous valid compound prescription orders, and on an established history between the prescriber and the patient and the compounder.”

Page 77 – Before the header “Sunscreen Ingredients”, insert the following:

“Staffing at Land Ports of Entry.—The Committee is concerned that USDA, FDA, and Customs and Border Protection are relying on historical data in determining their staffing models at Land Ports of Entry. Recent reports on agriculture imports show steep increases in the future, especially along the Southwest border and South Texas in particular. It is the sense of the Committee that these agencies should be utilizing forward looking data for their staffing models to ensure we have an appropriate workforce available in the future to inspect and certify this growth in agriculture imports as efficiently, safely and expeditiously as possible.”

Ag Cole
Agreed
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3/19

**AMENDMENT TO AGRICULTURE AND RURAL
DEVELOPMENT APPROPRIATIONS BILL
OFFERED BY MR. COLE OF OKLAHOMA AND MR.
BISHOP OF GEORGIA**

[FY 2017 Appropriations]

At the end of the bill (before the spending reduction account), insert the following:

- 1 SEC. _____. (a) None of the funds appropriated or
2 otherwise made available by this Act or any other Act with
3 respect to any fiscal year may, for each tobacco product
4 which the Secretary of Health and Human Services by
5 regulation under section 901(b) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 387a(b)) deems to
7 be subject to chapter IX of such Act, be used to treat—
- 8 (1) any reference in sections 905(j) or 910(a)
9 of such Act (21 U.S.C. 387e(j), 387j(a)) to Feb-
10 ruary 15, 2007, as other than a reference to the ef-
11 fective date of the regulation under which the to-
12 bacco product is deemed to be subject to the require-
13 ments of such chapter pursuant to section 901(b) of
14 such Act (21 U.S.C. 387a(b)); and
- 15 (2) any reference in such sections to 21 months
16 after the date of enactment of the Family Smoking

1 Prevention and Tobacco Control Act as other than
2 a reference to 21 months after the effective date of
3 such deeming regulation.

4 (b)(1) Notwithstanding any other provision of law,
5 not later than 12 months after the date on which vapor
6 products are deemed to be subject to the Federal Food,
7 Drug, and Cosmetic Act pursuant to section 901(b) of
8 that Act (21 U.S.C. 387a), the Secretary of Health and
9 Human Services shall issue a notice of proposed rule-
10 making to establish a product standard for vapor product
11 batteries pursuant to section 907 of that Act (21 U.S.C.
12 387g).

13 (2) Notwithstanding any other provision of law, not
14 later than 24 months after the date on which vapor prod-
15 ucts are deemed to be subject to the Federal Food, Drug,
16 and Cosmetic Act pursuant to section 901(b) of that Act
17 (21 U.S.C. 387a), the Secretary of Health and Human
18 Services shall promulgate a final tobacco product standard
19 for vapor product batteries pursuant to section 907 of that
20 Act (21 U.S.C. 387g).

21 (c) A vapor product shall be deemed to be misbranded
22 under section 903(a) of the Federal Food, Drug, and Cos-
23 mectic Act (21 U.S.C. 387c(a)) if the advertising with re-
24 spect to the vapor product is disseminated by a manufac-
25 turer, distributor, or retailer of the product in a news-

1 paper, magazine, periodical, or other publication (includ-
2 ing any publication of periodic or limited distribution)
3 other than an adult publication.

4 (d)(1) A retailer may only sell any vapor product in
5 a direct face-to-face exchange without the assistance of
6 any electronic or mechanical device (such as a vending ma-
7 chine).

8 (2) This subsection shall not apply with respect to
9 sales of vapor products conducted through—

10 (A) mail-order; or

11 (B) a vending machine or self-service display if, with
12 respect to the facility in which such vending machine or
13 display is located, the retailer of such products ensures
14 that no person under 18 years of age would be present
15 or be permitted to enter.

16 (3) A violation of this section is deemed to constitute
17 a violation of the Federal Food, Drug, and Cosmetic Act
18 relating to a tobacco product for purposes of section
19 303(f)(9) of such Act (21 U.S.C. 333(f)(9)).

20 (e)(1) Not later than 12 months after the date of en-
21 actment of this Act, the Secretary of Health and Human
22 Services shall promulgate final regulations to require that
23 the labeling of vapor products contain—

24 (A) the phrase “Keep Out of Reach of Children”;

25 (B) the phrase “Underage Sale Prohibited”; and

1 (C) an accurate statement of the nicotine content of
2 the vapor product.

3 (2) A vapor product whose label is in violation of the
4 regulations required by paragraph (1) is deemed to be mis-
5 branded under section 903 of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 387c).

7 (f)(1) Every person who owns or operates an estab-
8 lishment in any State engaged in the retail sale of a vapor
9 product shall register that establishment with the Sec-
10 retary of Health and Human Services within the later of
11 60 days after the date of enactment of this Act, or 30
12 days after first engaging in such retail sale.

13 (2) The requirements of this subsection do not apply
14 with respect to any establishment subject to an active reg-
15 istration under—

16 (A) any State law relating to tobacco products; or

17 (B) section 905 of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 387e).

19 (3) The Secretary shall make available for inspection,
20 to any person so requesting, any registration filed under
21 this section.

22 (g) In this section:

23 (1) The term “adult publication” means a newspaper,
24 magazine, periodical, or other publication—

1 (A) whose readers younger than 18 years of age
2 constitute 15 percent or less of the total readership
3 as measured by competent and reliable survey evi-
4 dence; and

5 (B) that is read by fewer than 2 million persons
6 younger than 18 years of age as measured by com-
7 petent and reliable survey evidence.

8 (2) The terms “label” and “labeling” have the mean-
9 ings given to such terms in section 201 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 321).

11 (3) The term “tobacco product” has the meaning
12 given to such term in section 201 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 321).

14 (4) The term “vapor product”—

15 (A) means any non-combustible product that
16 employs a heating element, power source, electronic
17 circuit, or other electronic, chemical, or mechanical
18 means, regardless of shape or size, to produce vapor
19 from nicotine in a solution or other form;

20 (B) includes any electronic cigarette, electronic
21 cigar, electronic cigarillo, electronic pipe, or similar
22 product or device, and any vapor cartridge or other
23 container of nicotine in a solution or other form; and

24 (C) does not include any product regulated as
25 a drug or device by the Food and Drug Administra-

1 tion under chapter V of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 21 U.S.C. 351 et
3 seq.).



Added to
25-
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**AMENDMENT TO AGRICULTURE AND RURAL
DEVELOPMENT APPROPRIATIONS BILL
OFFERED BY MR. FARR OF CALIFORNIA
AND MR. DENT OF PENNSYLVANIA**

At the end of the bill (before the spending reduction account), insert the following:

- 1 SEC. 7____. None of the funds made available in this
2 Act may be used to pay the salary or expenses of per-
3 sonnel—
- 4 (1) to inspect horses under section 3 of the
5 Federal Meat Inspection Act (21 U.S.C. 603);
- 6 (2) to inspect horses under section 903 of the
7 Federal Agriculture Improvement and Reform Act of
8 1996 (7 U.S.C. 1901 note; Public Law 104-127); or
- 9 (3) to implement or enforce section 352.19 of
10 title 9, Code of Federal Regulations (or a successor
11 regulation).



(Handwritten initials)

AG PALAZZO
AG Leads
VU

**AMENDMENT TO AGRICULTURE AND RURAL
DEVELOPMENT APPROPRIATIONS BILL, 2017
OFFERED BY MR. PALAZZO OF MISSISSIPPI**

At the end of the bill (before the spending reduction account), insert the following:

1 SEC. _____. None of the funds provided by this Act
2 shall be used to write, prepare, or publish an interim final
3 rule, or final rule, that would alter the definition of "staple
4 food" or "retail food store" as defined in section 271.2
5 of title 7 of the Code of Federal Regulations (January 1,
6 2016), or the approval of retail food stores and wholesale
7 food concerns in accordance with section 278.1 of title 7
8 of the Code of Federal Regulations (January 1, 2016),
9 except to change the variety of foods required, or the num-
10 ber of perishable items, to comply with section 3 of the
11 Food and Nutrition Act of 2008 as amended by sections
12 4002(a) and 4030(a)(4) of the Agricultural Act of 2014
13 (Public Law 113-79).

[Handwritten signature]

Ag Harris #1
Agreed to
VV

**AMENDMENT TO AGRICULTURE AND RURAL
DEVELOPMENT APPROPRIATIONS BILL
OFFERED BY MR. HARRIS OF MARYLAND**

At the end of the bill (before the spending reduction account), insert the following:

1 SEC. 7____. None of the funds made available by this
2 Act may be used by the Food and Drug Administration
3 to develop, issue, promote, or advance any guidelines or
4 regulations applicable to food manufacturers for popu-
5 lation-wide sodium reduction actions until the Centers for
6 Disease Control and Prevention or the National Academy
7 of Medicine completes a dietary reference intake report
8 with respect to sodium.

Agriculture - Valadao

agreed to
30-19

#9

**AMENDMENT TO AGRICULTURE AND RURAL
DEVELOPMENT APPROPRIATIONS BILL
OFFERED BY MR. VALADAO OF CALIFORNIA**

At the end of the bill (before the spending reduction account), insert the following:

1 SEC. ____ . None of the funds made available to the
2 Commodity Futures Trading Commission by this Act or
3 any other Act in the current fiscal year or any other fiscal
4 year may be used to pay the salaries and expenses of per-
5 sonnel to lower the de minimis quantity of swap dealing
6 established under section 1a(49)(D) of the Commodity Ex-
7 change Act (7 U.S.C. 1a(49)(D)) to less than
8 \$8,000,000,000.



#11

Lee Amndt. #2
AG 128-22

AMENDMENT TO AGRICULTURE APPROPRIATIONS

BILL

OFFERED BY MS. LEE OF CALIFORNIA

Page 2, line 14, reduce the first dollar amount by \$1,000,000.

Page 2, line 22, reduce the dollar amount by \$1,000,000.

Page 98, after line 6, add the following new section:

1 SEC. 7 ____ . For necessary expenses of the Secretary
2 of Agriculture to support projects that provide access to
3 healthy food in underserved areas, to create and preserve
4 quality jobs, and to revitalize low-income communities,
5 \$1,000,000, for the cost of loans and grants under the
6 Healthy Food Financing Initiative consistent with section
7 243 of the Department of Agriculture Reorganization Act
8 of 1994 (7 U.S.C. 6953), as added by section 4206 of
9 the Agricultural Act of 2014.



#12

Ag Harris #2
A-6-11-14
to
26-24

**AMENDMENT TO AGRICULTURE AND RURAL
DEVELOPMENT APPROPRIATIONS BILL
OFFERED BY MR. HARRIS OF MARYLAND**

At the end of the bill (before the spending reduction account), insert the following:

1 SEC. 7 ____ . None of the funds made available by this
2 or any other Act may be used to write, prepare, propose,
3 or publish a final rule or an interim final rule in further-
4 ance of, or otherwise to implement any regulations or
5 other regulatory requirements or policies that are identical
6 or similar in nature or application to the proposed rule
7 entitled "Implementation of Regulations Required Under
8 Title XI, of the Food, Conservation and Energy Act of
9 2008; Conduct in Violation of the Act" published by the
10 Department of Agriculture in the Federal Register on
11 June 22, 2010 (75 Fed. Reg. 35338 et seq.) unless the
12 combined annual cost to the economy of such rules does
13 not exceed \$100,000,000: *Provided*, That none of the
14 funds made available by this or any other Act may be used
15 to propose or publish a final or interim final rule in fur-
16 therance of, or otherwise to implement any regulations or
17 other regulatory requirements or policies that are identical
18 or similar in nature or application to section 201.2(1),

1 201.2(t), 201.2(u), 201.3(c), 201.210, 201.211, 201.213,
2 or 201.214, as proposed to be added to title 9 of the Code
3 of Federal Regulations by such proposed rule.



AG LOWEY 2

#14

agreed to
as amended
by Rogers #14a1
20-20

AMENDMENT TO AGRICULTURE AND RURAL
DEVELOPMENT APPROPRIATIONS BILL
OFFERED BY MRS. LOWEY OF NEW YORK

At the end of the bill (before the spending reduction
account), add the following:

1 TITLE VIII

2 DEPARTMENT OF HEALTH AND HUMAN

3 SERVICES

4 FOOD AND DRUG ADMINISTRATION

5 SALARIES AND EXPENSES

6 For an additional amount for "Salaries and Ex-

7 penses", \$10,000,000, to remain available until expended,

8 to prevent, prepare for, and respond to Zika virus, other

9 vector-borne diseases, or other infectious diseases and re-

10 lated health outcomes, domestically and internationally,

11 and to develop necessary medical countermeasures and

12 vaccines, including the review, regulation, and post market

13 surveillance of vaccines and therapies, and administrative

14 activities: *Provided*, That such amount is designated by

15 the Congress as an emergency requirement pursuant to

16 section 251(b)(2)(A)(i) of the Balanced Budget and

17 Emergency Deficit Control Act of 1985, except that such

18 amounts shall be available only if the President subse-

INSERT TEXT OF
Rogers #14a2

1 quently so designates such amounts and transmits such
2 designation to the Congress.

3 CENTERS FOR DISEASE CONTROL AND PREVENTION

4 CDC-WIDE ACTIVITIES AND PROGRAM SUPPORT

5 (INCLUDING TRANSFER OF FUNDS)

6 For an additional amount for "CDC-Wide Activities
7 and Program Support", \$828,000,000, to remain avail-
8 able until expended, to prevent, prepare for, and respond
9 to Zika virus, other vector-borne diseases, or other infec-
10 tious diseases and related health outcomes, domestically
11 and internationally; and to carry out titles II, III, and
12 XVII of the Public Health Service ("PHS") Act with re-
13 spect to domestic preparedness and global health: *Pro-*
14 *vided*, That products purchased with these funds may, at
15 the discretion of the Secretary of Health and Human
16 Services, be deposited in the Strategic National Stockpile
17 under section 319F-2 of the PHS Act: *Provided further*,
18 That funds may be used for purchase and insurance of
19 official motor vehicles in foreign countries: *Provided fur-*
20 *ther*, That the provisions in section 317S of the PHS Act
21 shall apply to the use of funds appropriated in this para-
22 graph as determined by the Director of the Centers for
23 Disease Control and Prevention ("CDC") to be appro-
24 priate: *Provided further*, That funds appropriated in this
25 paragraph may be used for grants for the construction,

1 alteration, or renovation of non-federally owned facilities
2 to improve preparedness and response capability at the
3 State and local level: *Provided further*, That funds appro-
4 priated in this paragraph may be used for acquisition of
5 real property (including long-term ground leases) and
6 equipment, and construction, demolition, or renovation of
7 facilities, including construction on leased land: *Provided*
8 *further*, That funds appropriated in this paragraph may
9 be transferred by the Director of CDC to other accounts
10 of the CDC for the purposes provided in this paragraph:
11 *Provided further*, That such transfer authority is in addi-
12 tion to any other transfer authority provided by law: *Pro-*
13 *vided further*, That, upon a determination that all or part
14 of the funds transferred from this appropriation are not
15 necessary for the purposes provided herein, such amounts
16 may be transferred back to this appropriation: *Provided*
17 *further*, That such amount is designated by the Congress
18 as an emergency requirement pursuant to section
19 251(b)(2)(A)(i) of the Balanced Budget and Emergency
20 Deficit Control Act of 1985, except that such amounts
21 shall be available only if the President subsequently so
22 designates such amounts and transmits such designation
23 to the Congress.

1 NATIONAL INSTITUTES OF HEALTH
2 NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS
3 DISEASES
4 For an additional amount for "National Institute of
5 Allergy and Infectious Diseases", \$130,000,000, to re-
6 main available until expended, to prevent, prepare for, and
7 respond to Zika virus, other vector-borne diseases, or
8 other infectious diseases and related health outcomes, do-
9 mestically and internationally, including expenses related
10 to carrying out section 301 and title IV of the PHS Act:
11 *Provided*, That such funds may be transferred by the Di-
12 rector of the National Institutes of Health ("NIH") to
13 other accounts of the NIH for the purposes provided in
14 this paragraph: *Provided further*, That such transfer au-
15 thority is in addition to any other transfer authority pro-
16 vided by law: *Provided further*, That, upon a determination
17 that all or part of the funds transferred from this appro-
18 priation are not necessary for the purposes provided here-
19 in, such amounts may be transferred back to this appro-
20 priation: *Provided further*, That such amount is designated
21 by the Congress as an emergency requirement pursuant
22 to section 251(b)(2)(A)(i) of the Balanced Budget and
23 Emergency Deficit Control Act of 1985, except that such
24 amounts shall be available only if the President subse-

1 quently so designates such amounts and transmits such
2 designation to the Congress.

3 OFFICE OF THE SECRETARY
4 PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY
5 FUND
6 (INCLUDING TRANSFER OF FUNDS)

7 For an additional amount for "Public Health and So-
8 cial Services Emergency Fund", \$295,000,000, to remain
9 available until expended, to prevent, prepare for, and re-
10 spond to Zika virus, other vector-borne diseases, or other
11 infectious diseases and related health outcomes, domesti-
12 cally and internationally; to develop necessary counter-
13 measures and vaccines, including the development and
14 purchase of vaccines, therapeutics, diagnostics, necessary
15 medical supplies, and administrative activities; for car-
16 rying out titles II, III, and XVII of the PHS Act with
17 respect to domestic preparedness and global health; and
18 for carrying out title III of the PHS Act and title V of
19 the Social Security Act to provide health care and related
20 services in areas affected by Zika virus: *Provided*, That
21 funds appropriated in this paragraph may be used to pro-
22 cure security countermeasures (as defined in section
23 319F-2(c)(1)(B) of the PHS Act, as amended by this
24 Act): *Provided further*, That paragraphs (1) and (7)(C)
25 of subsection (c) of section 319F-2 of the PHS Act, but

1 no other provisions of such section, shall apply to such
2 security countermeasures procured with funds appro-
3 priated in this paragraph: *Provided further*, That products
4 purchased with funds appropriated in this paragraph may,
5 at the discretion of the Secretary of Health and Human
6 Services, be deposited in the Strategic National Stockpile
7 under section 319F-2 of the PHS Act: *Provided further*,
8 That funds appropriated in this paragraph may be trans-
9 ferred to the fund authorized by section 319F-4 of the
10 PHS Act: *Provided further*, That funds appropriated in
11 this paragraph may, for purposes of providing primary
12 health services in areas affected by Zika virus, other vec-
13 tor-borne diseases, or other infectious diseases, be used to
14 assign National Health Service Corps (“NHSC”) mem-
15 bers to Puerto Rico and other Territories, notwithstanding
16 the assignment priorities and limitations in or under sec-
17 tions 333(a)(1)(D), 333(b), or 333A(a) of the PHS Act,
18 and to make NHSC Loan Repayment Program awards
19 under section 338B of such Act: *Provided further*, That
20 funds may be awarded for projects of regional and na-
21 tional significance in Puerto Rico and other Territories
22 authorized under section 501 of the Social Security Act,
23 notwithstanding section 502 of such Act: *Provided further*,
24 That funds may be used for the alteration or renovation
25 of non-federally owned facilities to improve preparedness

1 and response capability at the State and local level: *Pro-*
2 *vided further*, That funds appropriated in this paragraph
3 may be transferred to other appropriations of the Depart-
4 ment of Health and Human Services, as determined by
5 the Secretary to be appropriate, to be used for the pur-
6 poses specified in this paragraph: *Provided further*, That
7 any transfers of these funds shall be made in consultation
8 with the Office of Management and Budget: *Provided fur-*
9 *ther*, That the transfer authority provided in this para-
10 graph is in addition to any other transfer authority pro-
11 vided by law: *Provided further*, That, upon a determination
12 that all or part of the funds transferred from this appro-
13 priation are not necessary for the purposes provided here-
14 in, such amounts may be transferred back to this appro-
15 priation: *Provided further*, That such amount is designated
16 by the Congress as an emergency requirement pursuant
17 to section 251(b)(2)(A)(i) of the Balanced Budget and
18 Emergency Deficit Control Act of 1985, except that such
19 amounts shall be available only if the President subse-
20 quently so designates such amounts and transmits such
21 designation to the Congress.

22 GENERAL PROVISIONS

23 (INCLUDING TRANSFER OF FUNDS)

24 SEC. 801. For purposes of preventing, preparing for,
25 and responding to Zika virus, other vector-borne diseases,

1 or other infectious diseases and related health outcomes
2 domestically and internationally, the Secretary of Health
3 and Human Services may use funds provided in this Act—

4 (1) to acquire, lease, construct, alter, renovate,
5 equip, furnish, or manage facilities outside of the
6 United States, as necessary to conduct such pro-
7 grams, in consultation with the Secretary of State,
8 either directly for the use of the United States Gov-
9 ernment or for the use, pursuant to grants, direct
10 assistance, or cooperative agreements, of public or
11 nonprofit private institutions or agencies in partici-
12 pating foreign countries; and

13 (2) to enter into contracts with individuals for
14 the provision of personal services (as described in
15 section 104 of part 37 of title 48, Code of Federal
16 Regulations (48 CFR 37.104)), within the United
17 States and abroad: *Provided*, That such individuals
18 may not be deemed employees of the United States
19 for the purpose of any law administered by the Of-
20 fice of Personnel Management.

21 SEC. 802. Section 3304 of title 5, United States
22 Code, is amended by adding at the end the following new
23 subsection:

24 “(g) The heads of the Department of Health and
25 Human Services, Department of State, and the Agency

1 for International Development may appoint, without re-
2 gard to the provisions of sections 3309 through 3319, can-
3 didates needed for positions to perform critical work in
4 direct response to a public health threat requiring an im-
5 mediate response for which—

6 “(1) public notice has been given; and

7 “(2) the Secretary of Health and Human Serv-
8 ices has determined that such a public health threat
9 exists.”

10 SEC. 803. Funds appropriated by this Act may be
11 used to reimburse accounts administered by the Depart-
12 ment of Health and Human Services for obligations in-
13 curred for Zika virus response prior to the date of the
14 enactment of this Act.

15 SEC. 804. Funds appropriated to the Department of
16 Health and Human Services in this Act may be trans-
17 ferred to and merged with other Federal accounts for pur-
18 poses specified in this Act following consultation with the
19 Office of Management and Budget: *Provided*, That such
20 transfer authority shall be in addition to any other trans-
21 fer authority provided by law: *Provided further*, That,
22 upon a determination that all or part of the funds trans-
23 ferred from an appropriation are not necessary, such
24 amounts may be transferred back to that appropriation.

1 SEC. 805. Section 319F-2(e)(1)(B) of the Public
2 Health Service Act (42 U.S.C. 247d-6b(e)(1)(B)) is
3 amended—

4 (1) in clause (i)(III)(bb), by striking “; or” and
5 inserting a semicolon;

6 (2) in clause (ii), by striking the period and in-
7 serting “; or”; and

8 (3) by adding at the end the following new
9 clause:

10 “(iii)(I) the Secretary determines to
11 be a necessary countermeasure to diag-
12 nose, mitigate, prevent, or treat harm from
13 any infectious disease that may pose a
14 threat to the public health; and

15 “(II)(aa) is approved or cleared
16 under chapter V of the Federal Food,
17 Drug, and Cosmetic Act, or licensed
18 under section 351 of this Act; or

19 “(bb) is a countermeasure
20 for which the Secretary deter-
21 mines that sufficient and satis-
22 factory clinical experience or re-
23 search data (including data, if
24 available, from pre-clinical and
25 clinical trials) support a reason-

1 able conclusion that the counter-
2 measure will qualify for approval
3 or licensing within 10 years after
4 the date of a determination
5 under subclause (F).”.

6 SEC. 806. (a)(1) For purposes of title XIX of the So-
7 cial Security Act, for the one-year period beginning with
8 the first day of the first full fiscal quarter following the
9 date of the enactment of this section, the Federal medical
10 assistance percentage (“FMAP”) under section 1905(b)
11 of such Act for the Territories specified in paragraph (2)
12 shall be increased from 55 percent to 65 percent. Any net
13 increase in payment to such a territory under section
14 1903(a) of such Act, which is attributable to such in-
15 creased FMAP, shall be disregarded in applying sections
16 1108(f) and 1108(g) of such Act to the territory.

17 (2) The Territories specified in this paragraph are
18 the Commonwealth of Puerto Rico, the United States Vir-
19 gin Islands, Guam, American Samoa, and the Northern
20 Mariana Islands.

21 (b) With respect to the amount needed for purposes
22 of implementing the raised FMAP under subsection (a)
23 for each of fiscal years 2016 and 2017, such amount is
24 designated by the Congress as an emergency requirement
25 pursuant to section 251(b)(2)(A)(i) of the Balanced Budg-

1 et and Emergency Deficit Control Act of 1985, as amend-
2 ed, and such amount shall be available only if the Presi-
3 dent designates such amount as an emergency require-
4 ment pursuant to section 251(b)(2)(A)(i).

5 TITLE IX

6 DEPARTMENT OF STATE

7 ADMINISTRATION OF FOREIGN AFFAIRS

8 DIPLOMATIC AND CONSULAR PROGRAMS

9 For an additional amount for "Diplomatic and Con-
10 sular Programs", \$14,594,000, to remain available until
11 September 30, 2017, for necessary expenses to support re-
12 sponse efforts related to the Zika virus and related health
13 outcomes, other vector-borne diseases, or other infectious
14 diseases: *Provided*, That up to \$2,419,000 may be made
15 available for medical evacuation costs of any other Depart-
16 ment or agency of the United States under the Chief of
17 Mission authority, and may be transferred to any other
18 appropriation of such Department or agency for such
19 costs: *Provided further*, That such amount is designated
20 by the Congress as an emergency requirement pursuant
21 to section 251(b)(2)(A)(i) of the Balanced Budget and
22 Emergency Deficit Control Act of 1985, except that such
23 amounts shall be available only if the President subse-
24 quently so designates such amounts and transmits such
25 designation to the Congress.

1 EMERGENCIES IN THE DIPLOMATIC AND CONSULAR
2 SERVICE

3 For an additional amount for "Emergencies in the
4 Diplomatic and Consular Services", \$4,000,000 for nec-
5 essary expenses to support response efforts related to the
6 Zika virus and related health outcomes, other vector-borne
7 diseases, or other infectious diseases, to remain available
8 until expended: *Provided*, That such amount is designated
9 by the Congress as an emergency requirement pursuant
10 to section 251(b)(2)(A)(i) of the Balanced Budget and
11 Emergency Deficit Control Act of 1985, except that such
12 amounts shall be available only if the President subse-
13 quently so designates such amounts and transmits such
14 designation to the Congress.

15 REPATRIATION LOANS PROGRAM ACCOUNT

16 For an additional amount for "Repatriation Loans
17 Program Account" for the cost of direct loans,
18 \$1,000,000, to support the response efforts related to the
19 Zika virus and related health outcomes, other vector-borne
20 diseases, or other infectious diseases, to remain available
21 until expended: *Provided*, That such costs, including the
22 cost of modifying such loans, shall be as defined in section
23 502 of the Congressional Budget Act of 1974: *Provided*
24 *further*, That such funds are available to subsidize an addi-
25 tional amount of gross obligations for the principal

1 amount of direct loans not to exceed \$1,880,406: *Provided*
2 *further*, That such amount is designated by the Congress
3 as an emergency requirement pursuant to section
4 251(b)(2)(A)(i) of the Balanced Budget and Emergency
5 Deficit Control Act of 1985, except that such amounts
6 shall be available only if the President subsequently so
7 designates such amounts and transmits such designation
8 to the Congress.

9 UNITED STATES AGENCY FOR INTERNATIONAL
10 DEVELOPMENT

11 FUNDS APPROPRIATED TO THE PRESIDENT

12 OPERATING EXPENSES

13 For an additional amount for "Operating Expenses",
14 \$10,000,000, to remain available until September 30,
15 2017 for necessary expenses to support response efforts
16 related to the Zika virus and related health outcomes,
17 other vector-borne diseases, or other infectious diseases:
18 *Provided*, That such amounts are designated by the Con-
19 gress as an emergency requirement pursuant to section
20 251(b)(2)(A)(i) of the Balanced Budget and Emergency
21 Deficit Control Act of 1985, except that such amounts
22 shall be available only if the President subsequently so
23 designates such amounts and transmits such designation
24 to the Congress.

1 BILATERAL ECONOMIC ASSISTANCE
2 FUNDS APPROPRIATED TO THE PRESIDENT
3 GLOBAL HEALTH PROGRAMS

4 For an additional amount for "Global Health Pro-
5 grams", \$325,000,000, to remain available until ex-
6 pended, for necessary expenses for assistance or research
7 to prevent, treat, or otherwise respond to the Zika virus
8 and related health outcomes, other vector-borne diseases,
9 or other infectious diseases: *Provided*, That funds appro-
10 priated under this heading may be made available for
11 multi-year funding commitments to incentivize the devel-
12 opment of global health technologies: *Provided further*,
13 That such amounts are designated by the Congress as an
14 emergency requirement pursuant to section
15 251(b)(2)(A)(i) of the Balanced Budget and Emergency
16 Deficit Control Act of 1985, except that such amounts
17 shall be available only if the President subsequently so
18 designates such amounts and transmits such designation
19 to the Congress.

20 INTERNATIONAL SECURITY ASSISTANCE

21 DEPARTMENT OF STATE

22 NONPROLIFERATION, ANTI-TERRORISM, DEMINING AND
23 RELATED PROGRAMS

24 For an additional amount for "Nonproliferation,
25 Anti-Terrorism, Demining and Related Programs",

1 \$8,000,000, to remain available until September 30, 2017,
2 for necessary expenses to support response and research
3 efforts related to the Zika virus and related health out-
4 comes, other vector-borne diseases, or other infectious dis-
5 eases: *Provided*, That such amounts are designated by the
6 Congress as an emergency requirement pursuant to sec-
7 tion 251(b)(2)(A)(i) of the Balanced Budget and Emer-
8 gency Deficit Control Act of 1985, except that such
9 amounts shall be available only if the President subse-
10 quently so designates such amounts and transmits such
11 designation to the Congress.

MULTILATERAL ASSISTANCE

FUNDS APPROPRIATED TO THE PRESIDENT

INTERNATIONAL ORGANIZATIONS AND PROGRAMS

15 For an additional amount for "International Organi-
16 zations and Programs", \$13,500,000, to remain available
17 until September 30, 2017, for necessary expenses to sup-
18 port response and research efforts related to the Zika
19 virus and related health outcomes, other vector-borne dis-
20 eases, or other infectious diseases: *Provided*, That such
21 amounts are designated by the Congress as an emergency
22 requirement pursuant to section 251(b)(2)(A)(i) of the
23 Balanced Budget and Emergency Deficit Control Act of
24 1985, except that such amounts shall be available only if

1 the President subsequently so designates such amounts
2 and transmits such designation to the Congress.

3 GENERAL PROVISIONS

4 USE OF EBOLA BALANCES FOR OTHER INFECTIOUS 5 DISEASES

6 SEC. 901. Unobligated balances of amounts appro-
7 priated under title IX of the Department of State, Foreign
8 Operations, and Related Programs Appropriations Act,
9 2015 (division J of Public Law 113-235) shall also be
10 available for necessary expenses for operations, assistance,
11 or research to prevent, treat, or otherwise respond to the
12 Zika virus and related health outcomes, other vector-borne
13 diseases, or other infectious diseases: *Provided*, That
14 amounts repurposed pursuant to this section are des-
15 ignated by the Congress as an emergency requirement
16 pursuant to section 251(b)(2)(A)(i) of the Balanced Budg-
17 et and Emergency Deficit Control Act of 1985, except that
18 such amounts shall be available only if the President sub-
19 sequently so designates such amounts and transmits such
20 designation to the Congress.

21 TRANSFER AUTHORITY

22 SEC. 902. (a) Funds appropriated by this title under
23 the headings "Global Health Programs", "Nonprolifera-
24 tion, Anti-Terrorism, Demining and Related Programs",
25 "International Organizations and Programs", and "Oper-
26 ating Expenses" may be transferred to, and merged with,

1 funds appropriated by this title under such headings to
2 carry out the purposes of this Act.

3 (b) Funds appropriated by this title under the head-
4 ings "Diplomatic and Consular Programs", "Emergencies
5 in the Diplomatic and Consular Service", and "Repatri-
6 ation Loans Program Account" may be transferred to,
7 and merged with, funds appropriated by this title under
8 such headings to carry out the purposes of this Act.

9 (c) The transfer authorities provided by this section
10 are in addition to any other transfer authority provided
11 by law.

12 (d) Upon a determination that all or part of the funds
13 transferred pursuant to the authorities provided by this
14 section are not necessary for such purposes, such amounts
15 may be transferred back to such appropriations.

16 REIMBURSEMENT AUTHORITY

17 SEC. 903. Funds appropriated by this Act may be
18 used to reimburse accounts administered by the United
19 States Agency for International Development and the De-
20 partment of State for obligations incurred for Zika virus
21 response prior to the date of the enactment of this Act.

22 AVAILABILITY OF FUNDS FOR INTERNATIONAL

23 ORGANIZATIONS

24 SEC. 904. Section 307(a) of the Foreign Assistance
25 Act of 1961 shall not apply to funds appropriated by this
26 Act.

1 NOTWITHSTANDING AUTHORITY

2 SEC. 905. Funds appropriated or otherwise made
3 available under this Act and prior Acts making appropria-
4 tions for the Department of State, Foreign Operations,
5 and Related Programs that are made available to support
6 Zika virus response and related activities may be made
7 available notwithstanding any other provision of law.

8 PERSONAL SERVICE CONTRACTORS

9 SEC. 906. Funds available in this Act to support re-
10 sponse efforts related to the Zika virus and related health
11 outcomes, other vector-borne diseases, or other infectious
12 diseases may be used to enter into contracts with individ-
13 uals for the provision of personal services (as described
14 in section 104 of part 37 of title 48, Code of Federal Reg-
15 ulations (48 CFR 37.104)) in the United States or
16 abroad: *Provided*, That such individuals may not be
17 deemed employees of the United States for the purpose
18 of any law administered by the Office of Personnel Man-
19 agement.



#14a1

Rogers
April 4
30 2/6

AMENDMENT

**OFFERED BY MR. ROGERS OF KENTUCKY TO THE
AMENDMENT OFFERED BY MRS. LOWEY TO
THE AGRICULTURE, RURAL DEVELOPMENT,
FOOD AND DRUG ADMINISTRATION, AND RE-
LATED AGENCIES APPROPRIATIONS BILL**

Strike page 1, line 2, through page 19, line 20, and
insert:

1 “SEC. 801. Unobligated balances of amounts appro-
2 priated under title VI of the Departments of Labor,
3 Health and Human Services, Education and Related
4 Agencies Appropriations Act, 2015 (division G of Public
5 Law 113-235) and title IX of the Department of State,
6 Foreign Operations, and Related Programs Appropria-
7 tions Act, 2015 (division J of Public Law 113-235) shall
8 also be available for necessary expenses to prevent, pre-
9 pare for, and respond to Zika virus, domestically and
10 internationally: *Provided*, That such amounts are des-
11 ignated by the Congress as an emergency requirement
12 pursuant to section 251(b)(2)(A)(i) of the Balanced Budg-
13 et and Emergency Deficit Control Act of 1985, except that
14 such amounts shall be available only if the President sub-

- 1 sequently so designates such amounts and transmits such
- 2 designation to the Congress”.

