

AMENDMENT TO H.R. 6
OFFERED BY MR. UPTON OF MICHIGAN

(Page and line numbers refer to UPTON__005)

Page 17, after line 5, insert the following:

1 “(C) WORKFORCE.—In developing and
2 maintaining a strategic plan under this sub-
3 section, the Director of NIH shall ensure that
4 maintaining the biomedical workforce of the fu-
5 ture, including the participation by scientists
6 from groups traditionally underrepresented in
7 the scientific workforce, remains a priority.”.

Page 21, line 19, insert “PLAN PREPARATION AND”
before “IMPLEMENTATION OF”.

Page 21, line 21, insert “prepare a plan, including
time frames, and” after “shall”.

Page 22, line 8, strike “The Director” and insert
“Not later than two years after the date of enactment of
this Act, the Director”.

Page 24, after line 21, insert the following:

1 **SEC. 1029. SENSE OF CONGRESS ON INCREASED INCLUSION**
2 **OF UNDERREPRESENTED COMMUNITIES IN**
3 **CLINICAL TRIALS.**

4 It is the sense of Congress that the National Institute
5 on Minority Health and Health Disparities (NIMHD)
6 should include within its strategic plan ways to increase
7 representation of underrepresented communities in clinical
8 trials.

Page 41, line 19, strike “Secretary” and insert
“Comptroller General of the United States”.

Page 41, line 20, insert “and the Secretary” after
“Congress,”.

Page 42, line 24, strike “emphasis” and insert
“analysis”.

Page 51, line 13, strike “to sponsor” and insert
“that sponsor”.

Page 117, lines 6 through 7, strike “with the devel-
opment and approval of such a drug”.

Page 145, line 22, through page 151, line 6, amend
section 2123 to read as follows:

1 **SEC. 2123. ENCOURAGING THE DEVELOPMENT AND USE OF**
2 **NEW ANTIMICROBIAL DRUGS.**

3 (a) ADDITIONAL PAYMENT FOR NEW ANTI-
4 MICROBIAL DRUGS UNDER MEDICARE.—

5 (1) IN GENERAL.—Section 1886(d)(5) of the
6 Social Security Act (42 U.S.C. 1395ww(d)(5)) is
7 amended by adding at the end the following new
8 subparagraph:

9 “(M)(i) As part of the annual rulemaking under this
10 subsection for payment for subsection (d) hospitals for
11 each fiscal year beginning with fiscal year 2018, the Sec-
12 retary shall—

13 “(I) include publication of a list of the new
14 antimicrobial drugs for such fiscal year; and

15 “(II) with respect to discharges by eligible hos-
16 pitals that involve a drug so published, provide for
17 an additional payment to be made under this sub-
18 section in accordance with the provisions of this sub-
19 paragraph.

20 “(ii) Additional payments may not be made for a
21 drug under this subparagraph—

22 “(I) other than during the 5-fiscal-year period
23 beginning with the fiscal year in which the drug is
24 first included in the publication described in clause
25 (i)(I); and

1 “(II) with respect to which payment has ever
2 been made pursuant to subparagraph (K).

3 “(iii) For purposes of this subparagraph, the term
4 ‘new antimicrobial drug’ means a product that is approved
5 for use, or a product for which an indication is first ap-
6 proved for use, by the Food and Drug Administration on
7 or after December 1, 2014, and that the Food and Drug
8 Administration determines—

9 “(I) either—

10 “(aa) is intended to treat an infection
11 caused by, or likely to be caused by, a quali-
12 fying pathogen (as defined under section
13 505E(f) of the Federal Food, Drug, and Cos-
14 metic Act); or

15 “(bb) meets the definition of a qualified in-
16 fectionous disease product under section 505E(g)
17 of the Federal Food, Drug, and Cosmetic Act;
18 and

19 “(II) is intended to treat an infection—

20 “(aa) for which there is an unmet medical
21 need; and

22 “(bb) which is associated with high rates
23 of mortality or significant patient morbidity, as
24 determined in consultation with the Director of
25 the Centers for Disease Control and Prevention

1 and the infectious disease professional commu-
2 nity.

3 Such determination may be revoked only upon a finding
4 that the request for such determination contained an un-
5 true statement of material fact.

6 “(iv) For purposes of this subparagraph, the term ‘el-
7 igible hospital’ means a subsection (d) hospital that par-
8 ticipates in the National Healthcare Safety Network of the
9 Centers for Disease Control and Prevention (or, to the ex-
10 tent a similar surveillance system reporting program that
11 includes reporting about antimicrobial drugs is determined
12 by the Secretary to be available to such hospitals, such
13 similar surveillance system as the Secretary may specify).

14 “(v)(I) Subject to the succeeding provisions of this
15 clause, the additional payment under this subparagraph,
16 with respect to a drug, shall be in the amount provided
17 for such drug under section 1847A.

18 “(II) The Secretary shall, as part of the rulemaking
19 referred to in clause (i) for each fiscal year, estimate—

20 “(aa) the total amount of the additional pay-
21 ments that will be made under this subsection pur-
22 suant to this subparagraph for discharges in such
23 fiscal year without regard to the application of sub-
24 clause (III); and

1 “(bb) the total program payments to be made
2 under this subsection for all discharges in such fiscal
3 year.

4 “(III) If the estimated total amount described in sub-
5 clause (II)(aa) for a fiscal year exceeds the applicable per-
6 centage of the estimated total program payments de-
7 scribed in subclause (II)(bb) for such fiscal year, the Sec-
8 retary shall reduce in a pro rata manner the amount of
9 each additional payment under this subsection pursuant
10 to this subparagraph for such fiscal year in order to en-
11 sure that the total amount of the additional payments
12 under this subsection pursuant to this subparagraph for
13 such fiscal year do not exceed the applicable percentage
14 of the estimated total program payments described in sub-
15 clause (II)(bb) for such fiscal year.

16 “(IV) For purposes of subclause (III), the term ‘ap-
17 plicable percentage’ means 0.03 percent.”.

18 (2) CONFORMING AMENDMENTS.—

19 (A) NO DUPLICATIVE NTAP PAYMENTS.—
20 Section 1886(d)(5)(K)(vi) of the Social Security
21 Act (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amend-
22 ed by inserting “if additional payment has
23 never been made under this subsection pursu-
24 ant to subparagraph (M) with respect to the

1 service or technology” after “if the service or
2 technology”.

3 (B) ACCESS TO PRICE INFORMATION.—
4 Section 1927(b)(3)(A)(iii) of the Social Security
5 Act (42 U.S.C. 1396r-8(b)(3)(A)(iii)) is
6 amended—

7 (i) in subclause (II), by inserting “, or
8 under section 1886(d) pursuant to para-
9 graph (5)(M) of such section,” after
10 “1847A,”; and

11 (ii) in the matter following subclause
12 (III), by inserting “or section
13 1886(d)(5)(M)” after
14 “1881(b)(13)(A)(ii)”.

15 (b) STUDY AND REPORT ON REMOVING BARRIERS TO
16 DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS.—

17 (1) STUDY.—The Comptroller General of the
18 United States shall, in consultation with the Direc-
19 tor of the National Institutes of Health, the Com-
20 missioner of Food and Drugs, and the Director of
21 the Centers for Disease Control and Prevention, con-
22 duct a study to—

23 (A) identify and examine the barriers that
24 prevent the development of new antimicrobial
25 drugs, as defined in section 1886(d)(5)(M)(iii)

1 of the Social Security Act (42 U.S.C.
2 1395ww(d)(5)(M)(iii)); and

3 (B) develop recommendations for actions
4 to be taken in order to overcome any barriers
5 identified under subparagraph (A).

6 (2) REPORT.—Not later than 1 year after the
7 date of the enactment of this Act, the Comptroller
8 General shall submit to Congress a report on the
9 study conducted under paragraph (1).

Page 181, line 6, through page 193, line 20, amend
section 2221 to read as follows:

10 **SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

11 (a) ESTABLISHMENT OF THIRD-PARTY QUALITY
12 SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Fed-
13 eral Food, Drug, and Cosmetic Act is amended by insert-
14 ing after section 524A (21 U.S.C. 360n–1) the following
15 new section:

16 **“SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

17 “(a) ACCREDITATION AND ASSESSMENT.—

18 “(1) IN GENERAL; CERTIFICATION OF DEVICE
19 QUALITY SYSTEM.—The Secretary shall in accord-
20 ance with this section establish a third-party quality
21 system assessment program—

22 “(A) to accredit persons to assess whether
23 a requestor’s quality system, including its de-

1 sign controls, can reasonably assure the safety
2 and effectiveness of in-scope devices subject to
3 device-related changes (as defined in paragraph
4 (2));

5 “(B) under which accredited persons shall
6 as applicable certify that a requestor’s quality
7 system meets the criteria issued under para-
8 graph (5) with respect to the in-scope devices at
9 issue; and

10 “(C) under which the Secretary shall rely
11 on such certifications for purposes of deter-
12 mining the safety and effectiveness (or as appli-
13 cable, substantial equivalence) of in-scope de-
14 vices subject to the device-related changes in-
15 volved, in lieu of compliance with the following
16 submission requirements:

17 “(i) A premarket notification (as de-
18 fined in paragraph (2)).

19 “(ii) A thirty-day notice (as defined in
20 paragraph (2)).

21 “(iii) A Special PMA supplement (as
22 defined in paragraph (2)).

23 “(2) DEFINITIONS.—For purposes of this sec-
24 tion—

1 “(A) the term ‘device-related changes’
2 means changes made by a requestor with re-
3 spect to in-scope devices, which are—

4 “(i) changes to a device found to be
5 substantially equivalent under sections
6 513(i) and 510(k) to a predicate device,
7 that—

8 “(I) would otherwise be subject
9 to a premarket notification; and

10 “(II) do not alter—

11 “(aa) the intended use of
12 the changed device; or

13 “(bb) the fundamental sci-
14 entific technology of such device;

15 “(ii) manufacturing changes subject
16 to a 30-day notice;

17 “(iii) changes that qualify for a Spe-
18 cial PMA Supplement; and

19 “(iv) such other changes relating to
20 the devices or the device manufacturing
21 process as the Secretary determines appro-
22 priate;

23 “(B) the term ‘in-scope device’ means a
24 device within the scope of devices agreed to by
25 the requestor and the accredited person for pur-

1 poses of a request for certification under this
2 section;

3 “(C) the term ‘premarket notification’
4 means a premarket notification under section
5 510(k);

6 “(D) the term ‘quality system’ means the
7 methods used in, and the facilities and controls
8 used for, the design, manufacture, packaging,
9 labeling, storage, installation, and servicing of
10 devices, as described in section 520(f);

11 “(E) the term ‘requestor’ means a device
12 manufacturer that is seeking certification under
13 this section of a quality system used by such
14 manufacturer;

15 “(F) the term ‘Special PMA’ means a Spe-
16 cial PMA supplement under section 814.39(d)
17 of title 21, Code of Federal Regulations (or any
18 successor regulations); and

19 “(G) the term ‘thirty-day notice’ means a
20 notice described in section 515(d)(6).

21 “(3) ACCREDITATION PROCESS; ACCREDITATION
22 RENEWAL.—Except as inconsistent with this section,
23 the process and qualifications for accreditation of
24 persons and renewal of such accreditation under sec-
25 tion 704(g) shall apply with respect to accreditation

1 of persons and renewal of such accreditation under
2 this section.

3 “(4) USE OF ACCREDITED PARTIES TO CON-
4 DUCT ASSESSMENTS.—

5 “(A) INITIATION OF ASSESSMENT SERV-
6 ICES.—

7 “(i) DATE ASSESSMENTS AUTHOR-
8 IZED.—Beginning after issuance of the
9 final guidance under paragraph (5), an ac-
10 credited person may conduct an assess-
11 ment under this section.

12 “(ii) INITIATION OF ASSESSMENTS.—
13 Use of one or more accredited persons to
14 assess a requestor’s quality system under
15 this section with respect to in-scope devices
16 shall be at the initiation of the person who
17 registers and lists the devices at issue
18 under section 510.

19 “(B) COMPENSATION.—Compensation for
20 such accredited persons shall—

21 “(i) be determined by agreement be-
22 tween the accredited person and the person
23 who engages the services of the accredited
24 person; and

1 “(ii) be paid by the person who en-
2 gages such services.

3 “(C) ACCREDITED PERSON SELECTION.—

4 Each person who chooses to use an accredited
5 person to assess a requestor’s quality system,
6 as described in this section, shall select the ac-
7 credited person from a list of such persons pub-
8 lished by the Secretary in accordance with sec-
9 tion 704(g)(4).

10 “(5) GUIDANCE; CRITERIA FOR CERTIFI-
11 CATION.—

12 “(A) IN GENERAL.—The criteria for cer-
13 tification of a quality system under this section
14 shall be as specified by the Secretary in guid-
15 ance issued under this paragraph.

16 “(B) CONTENTS; CERTIFICATION CRI-
17 TERIA.—The guidance under this paragraph
18 shall include specification of—

19 “(i) evaluative criteria to be used by
20 an accredited person to assess and as ap-
21 plicable certify a requestor’s quality system
22 under this section with respect to in-scope
23 devices; and

1 “(ii) criteria for accredited persons to
2 apply a waiver of and exemptions from the
3 certification criteria under clause (i).

4 “(C) TIMEFRAME FOR ISSUING GUID-
5 ANCE.—The Secretary shall issue under this
6 paragraph—

7 “(i) draft guidance not later than 12
8 months after the enactment of the 21st
9 Century Cures Act; and

10 “(ii) final guidance not later than 12
11 months after issuance of the draft guid-
12 ance under clause (i).

13 “(b) USE OF THIRD-PARTY ASSESSMENT.—

14 “(1) ASSESSMENT SUMMARY; CERTIFI-
15 CATION.—

16 “(A) SUBMISSION OF ASSESSMENT TO SEC-
17 RETARY.—An accredited person who assesses a
18 requestor’s quality system under subsection (a)
19 shall submit to the Secretary a summary of the
20 assessment—

21 “(i) within 30 days of the assessment;
22 and

23 “(ii) which as applicable shall in-
24 clude—

1 “(I) the accredited person’s cer-
2 tification that the requestor has satis-
3 fied the criteria issued under sub-
4 section (a)(5) for quality system cer-
5 tification with respect to the in-scope
6 devices at issue ; and

7 “(II) any waivers or exemptions
8 from such criteria applied by the ac-
9 credited person.

10 “(B) TREATMENT OF ASSESSMENTS.—
11 Subject to action by the Secretary under sub-
12 paragraph (C), with respect to assessments
13 which include a certification under this sec-
14 tion—

15 “(i) the Secretary’s review of the as-
16 sessment summary shall be deemed com-
17 plete on the day that is 30 days after the
18 date on which the Secretary receives the
19 summary under subparagraph (A); and

20 “(ii) the assessment summary and
21 certification of the requestor shall be
22 deemed accepted by the Secretary on such
23 30th day.

24 “(C) ACTIONS BY SECRETARY.—

1 “(i) IN GENERAL.—Within 30 days of
2 receiving an assessment summary and cer-
3 tification under subparagraph (A), the Sec-
4 retary may, by written notice to the ac-
5 credited person submitting such assess-
6 ment certification, deem any such certifi-
7 cation to be provisional beyond such 30-
8 day period, suspended pending further re-
9 view by the Secretary, or otherwise quali-
10 fied or cancelled, based on the Secretary’s
11 determination that (as applicable)—

12 “(I) additional information is
13 needed to support such certification;

14 “(II) such assessment or certifi-
15 cation is unwarranted; or

16 “(III) such action with regard to
17 the certification is otherwise justified
18 according to such factors and criteria
19 as the Secretary finds appropriate.

20 “(ii) ACCEPTANCE OF CERTIFI-
21 CATION.—If following action by the Sec-
22 retary under clause (i) with respect to a
23 certification, the Secretary determines that
24 such certification is acceptable, the Sec-
25 retary shall issue written notice to the ap-

1 plicable accredited person indicating such
2 acceptance.

3 “(2) NOTIFICATIONS TO SECRETARY BY CER-
4 TIFIED REQUESTORS OR ACCREDITED PERSONS FOR
5 PROGRAM EVALUATION PURPOSES.—

6 “(A) ANNUAL SUMMARY REPORT FOR DE-
7 VICE-RELATED CHANGES OTHERWISE SUBJECT
8 TO PREMARKET NOTIFICATION.—A requestor
9 certified under this section that effectuates de-
10 vice-related changes with respect to in-scope de-
11 vices, without prior submission of a premarket
12 notification, shall ensure that an annual sum-
13 mary report is submitted to the Secretary by
14 the accredited person which—

15 “(i) describe the changes made to the
16 in-scope device; and

17 “(ii) indicate the effective dates of
18 such changes.

19 “(B) PERIODIC NOTIFICATION FOR MANU-
20 FACTURING CHANGES OTHERWISE SUBJECT TO
21 THIRTY-DAY NOTICE.—A requestor certified
22 under this section that effectuates device-re-
23 lated changes with respect to in-scope devices,
24 without prior submission of a thirty-day notice,
25 shall provide notification to the Secretary of

1 such changes in the requestor's next periodic
2 report under section 814.84(b) of title 21, Code
3 of Federal Regulations (or any successor regu-
4 lation). Such notification shall—

5 “(i) describe the changes made; and

6 “(ii) indicate the effective dates of
7 such changes.

8 “(C) PERIODIC NOTIFICATION FOR DE-
9 VICE-RELATED CHANGES OTHERWISE SUBJECT
10 TO SPECIAL PMA SUPPLEMENT.—A requestor
11 certified under this section that effectuates de-
12 vice-related changes with respect to in-scope de-
13 vices, without prior submission of a Special
14 PMA Supplement, shall provide notification to
15 the Secretary of such changes in the requestor's
16 next periodic report under section 814.84(b) of
17 title 21, Code of Federal Regulations (or any
18 successor regulation). Such notification shall—

19 “(i) describe the changes made, in-
20 cluding a full explanation of the basis for
21 the changes; and

22 “(ii) indicate the effective dates of
23 such changes.

24 “(D) USE OF NOTIFICATIONS FOR PRO-
25 GRAM EVALUATION PURPOSES.—Information

1 submitted to the Secretary under subpara-
2 graphs (A) through (C) shall be used by the
3 Secretary for purposes of the program evalua-
4 tion under subsection (d).

5 “(c) DURATION AND EFFECT OF CERTIFICATION.—

6 A certification under this section—

7 “(1) shall remain in effect for a period of two
8 years from the date such certification is accepted by
9 the Secretary, subject to paragraph (6);

10 “(2) may be renewed through the process de-
11 scribed in subsection (a)(3);

12 “(3) shall continue to apply with respect to de-
13 vice-related changes made during such two-year pe-
14 riod, provided the certification remains in effect, ir-
15 respective of whether such certification is renewed
16 after such two-year period;

17 “(4) shall have no effect on the need to comply
18 with applicable submission requirements specified in
19 subsection (a)(1)(C) with respect to any change per-
20 taining to in-scope devices which is not a device-re-
21 lated change under subsection (a)(2);

22 “(5) shall have no effect on the authority of the
23 Secretary to conduct an inspection or otherwise de-
24 termine the requestor’s conformance with the appli-
25 cable requirements of this Act; and

1 “(6) may be revoked by the Secretary upon a
2 determination that the requestor’s quality system no
3 longer meets the certification criteria issued under
4 subsection (a)(5) with respect to the in-scope devices
5 at issue.

6 The Secretary shall provide written notification to the re-
7 questor of a revocation pursuant to paragraph (6) within
8 10 working days of the determination described in such
9 paragraph. Upon receipt of the written notification, the
10 requestor shall satisfy the applicable submission require-
11 ments specified in subsection (a)(1)(C) for any device-re-
12 lated changes effectuated after the date of such deter-
13 mination. After such revocation, such requestor is eligible
14 to seek re-certification under this section of its quality sys-
15 tem.

16 “(d) PROGRAM EVALUATION; SUNSET.—

17 “(1) PROGRAM EVALUATION AND REPORT.—

18 “(A) EVALUATION.—The Secretary shall
19 complete an evaluation of the third-party qual-
20 ity system assessment program under this sec-
21 tion no later than January 31, 2021, based
22 on—

23 “(i) analysis of information from a
24 representative group of device manufactur-
25 ers obtained from notifications provided by

1 certified requestors or accredited persons
2 under subsection (b)(2); and

3 “(ii) such other available information
4 and data as the Secretary determines ap-
5 propriate.

6 “(B) REPORT.—No later than one year
7 after completing the evaluation under subpara-
8 graph (A), the Secretary shall issue a report of
9 the evaluation’s findings on the website of the
10 Food and Drug Administration, which shall in-
11 clude the Secretary’s recommendations with re-
12 spect to continuation and as applicable expan-
13 sion of the program under this section to en-
14 compass—

15 “(i) device submissions beyond those
16 identified in subsection (a)(1)(C); and

17 “(ii) device changes beyond those de-
18 scribed in subsection (a)(2)(A). .

19 “(2) SUNSET.—This section shall cease to be
20 effective October 1, 2022.

21 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
22 tion shall be construed to limit the authority of the Sec-
23 retary to request and review the complete assessment of
24 a certified requestor under this section on a for-cause
25 basis.”.

1 (b) CONFORMING AMENDMENTS.—

2 (1) REQUIREMENTS FOR PREMARKET AP-
3 PROVAL SUPPLEMENTS.—Section 515(d)(6)(A)(i) of
4 the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 360e(d)(6)(A)(i)) is amended by inserting “,
6 subject to section 524B,” after “that affects safety
7 or effectiveness”.

8 (2) REQUIREMENTS FOR THIRTY-DAY NO-
9 TICE.—Section 515(d)(6)(A)(ii) of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C.
11 360e(d)(6)(A)(ii)) is amended by inserting “, subject
12 to section 524B,” after “the date on which the Sec-
13 retary receives the notice”.

14 (3) REQUIREMENTS FOR PREMARKET NOTIFI-
15 CATION; TECHNICAL CORRECTION TO REFERENCE
16 TO SECTION 510(K).—Section 510(l) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is
18 amended by striking “of this subsection under sub-
19 section (m)” and inserting “of subsection (k) under
20 subsection (m) or section 524B”.

21 (4) MISBRANDED DEVICES.—Section 502(t) of
22 the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 352(t)) is amended by inserting “or 524B”
24 after “section 519”.

Page 215, line 17, insert “, the FDA Human Subject Regulations,” after “the HHS Human Subject Regulations”.

Page 216, line 18, strike “12 months” and insert “36 months”.

Page 218, line 25, strike “subject to clause (ii),”.

Page 218, after line 14, insert the following new subsection (and make such conforming changes as may be necessary):

1 (e) DRAFT NIH POLICY.—Not later than 12 months
2 after the date of enactment of this Act, the Secretary, act-
3 ing through the Director of the National Institutes of
4 Health, shall finalize the draft policy entitled “Draft NIH
5 Policy on Use of a Single Institutional Review Board for
6 Multi-Site Research”.

Page 219, lines 10 through 12, strike “as applicable to the human subjects involved in research described in subparagraph (B)” and insert “as applicable to research that is subject to the FDA Human Subject Regulations”.

Page 219, line 17, through page 220, line 7, strike paragraph (2).

Page 220, line 8, strike “(3)” and insert “(2)”.

Page 229, after line 14, insert the following:

1 **SEC. 2285. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**
2 **NICAL, AND PROFESSIONAL PERSONNEL.**

3 (a) IN GENERAL.—The Federal Food, Drug, and
4 Cosmetic Act is amended by inserting after section 714
5 (21 U.S.C. 379d–3) the following:

6 **“SEC. 714A. ADDITIONAL HIRING AUTHORITY.**

7 “(a) IN GENERAL.—The Secretary may, without re-
8 gard to the provisions of title 5, United States Code, gov-
9 erning appointments in the competitive service, appoint
10 qualified candidates to scientific, technical, or professional
11 positions within the following centers of the Food and
12 Drug Administration:

13 “(1) The Center for Drug Evaluation and Re-
14 search.

15 “(2) The Center for Biologics Evaluation and
16 Research.

17 “(3) The Center for Devices and Radiological
18 Health.

19 Such positions shall be within the competitive service.

20 “(b) COMPENSATION.—

21 “(1) IN GENERAL.—Notwithstanding any other
22 provision of law, including any requirement with re-
23 spect to General Schedule pay rates under sub-
24 chapter III of chapter 53 of title 5, United States

1 Code, and consistent with the requirements of para-
2 graph (2), the Secretary may determine and fix—

3 “(A) the annual rate of pay of any indi-
4 vidual appointed under subsection (a); and

5 “(B) for purposes of retaining qualified
6 employees, the annual rate of pay for any high-
7 ly qualified scientific, technical, or professional
8 personnel appointed to a position at any of the
9 centers listed under subsection (a) before the
10 date of enactment of this section.

11 “(2) LIMITATION.—The annual rate of pay es-
12 tablished pursuant to paragraph (1) may not exceed
13 the annual rate of pay of the President.

14 “(c) SUNSET.—The authority to appoint employees
15 under this section shall terminate on September 30, 2022.

16 “(d) REPORT.—

17 “(1) IN GENERAL.—Not later than September
18 30, 2021, the Secretary shall submit a report to
19 Congress that examines the extent to which the au-
20 thority to appoint and retain personnel under this
21 section enhanced the Food and Drug Administra-
22 tion’s ability to meet the agency’s critical need for
23 highly qualified individuals for scientific, technical,
24 or professional positions.

1 “(2) RECOMMENDATIONS.—The report under
2 paragraph (1) shall include the recommendations of
3 the Secretary on—

4 “(A) whether the authority to appoint per-
5 sonnel under this section should be reauthor-
6 ized; and

7 “(B) other personnel authorities that
8 would help the Food and Drug Administration
9 to better recruit and retain highly qualified in-
10 dividuals for scientific, technical, or professional
11 positions in the agency’s medical product cen-
12 ters.”.

13 (b) RULE OF CONSTRUCTION.—The authority pro-
14 vided by section 714A of the Federal Food, Drug, and
15 Cosmetic Act (as added by subsection (a)) shall not be
16 construed to affect the authority provided under section
17 714 of such Act.

On page 229, after line 14, at the end of title II,
add the following:

1 **Subtitle Q—Exempting From**
2 **Sequestration Certain Use Fees**

3 **SEC. 2301. EXEMPTING FROM SEQUESTRATION CERTAIN**
4 **USER FEES OF FOOD AND DRUG ADMINIS-**
5 **TRATION.**

6 The Balanced Budget and Emergency Deficit Control
7 Act of 1985 is amended—

8 (1) in section 255(g)(1)(A) (2 U.S.C.
9 905(g)(1)(A)), by inserting after “Financial Agent
10 Services” the following new item:

11 “Food and Drug Administration, Salaries
12 and Expenses, but only the portion of appro-
13 priations under such account corresponding to
14 fees collected under sections 736, 738, 740,
15 741, 744B, and 744H of the Federal Food,
16 Drug, and Cosmetic Act (75–9911–0–1–554)”;
17 and

18 (2) in section 256(h) (2 U.S.C. 906(h)), by
19 adding at the end the following new paragraph:

20 “(5) Notwithstanding any other provision of the
21 law, this subsection shall not apply with respect to
22 the portion of administrative expenses incurred by
23 the Food and Drug Administration that are funded
24 through fees collected under sections 736, 738, 740,

1 741, 744B, and 744H of the Federal Food, Drug,
2 and Cosmetic Act.”.

Page 234, after line 23, insert the following:

3 “(5) ALLOWANCE FOR VARIATIONS.—Standards
4 developed pursuant to a contract under this sub-
5 section, and the methods to test such standards,
6 shall allow for variations on such standards as long
7 as such variations are consistent with the standards
8 so developed under this section.”.

Page 235, line 8, insert “, and methods to test such
standards,” after “standards”.

Page 235, lines 12 and 13 strike “, in consultation
with the National Coordinator,”.

Page 235, line 20, insert “and methods to test such
standards” after “criteria”.

Page 235, after line 25, insert the following:

9 “(3) MULTIPLE METHODS TO TEST INTEROPER-
10 ABILITY STANDARDS.—For the purposes of devel-
11 oping methods to test interoperability standards for
12 adoption under section 3004, the Secretary shall en-
13 sure that contracts under this section allow for mul-
14 tiple methods to test such standards to account for

1 variations in the adoption of such standards that do
2 not conflict with section 3010(a).

Page 239, lines 9 and 10, strike “the National Coordinator and”.

Page 255, line 21, strike “Inspector General and”.

Page 277, strike line 17 and all that follows through page 280, line 10 and make such conforming amendments as are necessary.

Page 309, after line 14, insert the following:

3 **TITLE IV—MEDICAID, MEDI-**
4 **CARE, AND OTHER REFORMS**
5 **Subtitle A—Medicaid and Medicare**
6 **Reforms**

7 **SEC. 4001. LIMITING FEDERAL MEDICAID REIMBURSEMENT**
8 **TO STATES FOR DURABLE MEDICAL EQUIP-**
9 **MENT (DME) TO MEDICARE PAYMENT RATES.**

10 (a) MEDICAID REIMBURSEMENT.—

11 (1) IN GENERAL.—Section 1903(i) of the Social
12 Security Act (42 U.S.C. 1396b(i)) is amended—

13 (A) in paragraph (25), by striking “or” at
14 the end;

15 (B) in paragraph (26), by striking the pe-
16 riod at the end and inserting “; or”; and

1 (C) by inserting after paragraph (26) the
2 following new paragraph:

3 “(27) with respect to any amounts expended by
4 the State on the basis of a fee schedule for items de-
5 scribed in section 1861(n), as determined in the ag-
6 gregate with respect to each class of such items as
7 defined by the Secretary, in excess of the aggregate
8 amount, if any, that would be paid for such items
9 within such class on a fee-for-service basis under the
10 program under part B of title XVIII, including, as
11 applicable, under a competitive acquisition program
12 under section 1847 in an area of the State.”.

13 (2) EFFECTIVE DATE.—The amendments made
14 by this subsection shall be effective with respect to
15 payments for items furnished on or after January 1,
16 2020.

17 (b) MEDICARE OMBUDSMAN.—Section 1808(c) of the
18 Social Security Act (42 U.S.C. 1395b(c)), as amended by
19 section 3101, is further amended by adding at the end
20 the following new paragraph:

21 “(5) MONITORING DME REIMBURSEMENT
22 UNDER MEDICAID.—The ombudsmen under each of
23 paragraphs (1) and (4) shall evaluate the impact of
24 the competitive acquisition program under section
25 1847, including as applied under section

1 1903(i)(27), on beneficiary health status and health
2 outcomes.”.

3 **SEC. 4002. MEDICARE PAYMENT INCENTIVE FOR THE TRAN-**
4 **SITION FROM TRADITIONAL X-RAY IMAGING**
5 **TO DIGITAL RADIOGRAPHY AND OTHER**
6 **MEDICARE IMAGING PAYMENT PROVISION.**

7 (a) PHYSICIAN FEE SCHEDULE.—

8 (1) PAYMENT INCENTIVE FOR TRANSITION.—

9 (A) IN GENERAL.—Section 1848(b) of the
10 Social Security Act (42 U.S.C. 1395w–4(b)) is
11 amended by adding at the end the following
12 new paragraph:

13 “(9) SPECIAL RULE TO INCENTIVIZE TRANSI-
14 TION FROM TRADITIONAL X-RAY IMAGING TO DIG-
15 ITAL RADIOGRAPHY.—

16 “(A) LIMITATION ON PAYMENT FOR FILM
17 X-RAY IMAGING SERVICES.—In the case of im-
18 aging services that are X-rays taken using film
19 and that are furnished during 2017 or a subse-
20 quent year, the payment amount for the tech-
21 nical component (including the technical compo-
22 nent portion of a global fee) of such services
23 that would otherwise be determined under this
24 section (without application of this paragraph
25 and before application of any other adjustment

1 under this section) for such year shall be re-
2 duced by 20 percent.

3 “(B) PHASED-IN LIMITATION ON PAYMENT
4 FOR COMPUTED RADIOGRAPHY IMAGING SERV-
5 ICES.—In the case of imaging services that are
6 X-rays taken using computed radiography tech-
7 nology—

8 “(i) in the case of such services fur-
9 nished during 2018, 2019, 2020, 2021, or
10 2022 the payment amount for the tech-
11 nical component (including the technical
12 component portion of a global fee) of such
13 services that would otherwise be deter-
14 mined under this section (without applica-
15 tion of this paragraph and before applica-
16 tion of any other adjustment under this
17 section) for such year shall be reduced by
18 7 percent; and

19 “(ii) in the case of such services fur-
20 nished during 2023 or a subsequent year,
21 the payment amount for the technical com-
22 ponent (including the technical component
23 portion of a global fee) of such services
24 that would otherwise be determined under
25 this section (without application of this

1 paragraph and before application of any
2 other adjustment under this section) for
3 such year shall be reduced by 10 percent.

4 “(C) COMPUTED RADIOGRAPHY TECH-
5 NOLOGY DEFINED.—For purposes of this para-
6 graph, the term ‘computed radiography tech-
7 nology’ means cassette-based imaging which
8 utilizes an imaging plate to create the image in-
9 volved.

10 “(D) IMPLEMENTATION.—In order to im-
11 plement this paragraph, the Secretary shall
12 adopt appropriate mechanisms which may in-
13 clude use of modifiers.”.

14 (B) EXEMPTION FROM BUDGET NEU-
15 TRALITY.—Section 1848(c)(2)(B)(v) of the So-
16 cial Security Act (42 U.S.C. 1395w-
17 4(c)(2)(B)(v)) is amended, by adding at the end
18 the following new subclause:

19 “(X) REDUCED EXPENDITURES
20 ATTRIBUTABLE TO INCENTIVES TO
21 TRANSITION TO DIGITAL RADIOG-
22 RAPHY.—Effective for fee schedules
23 established beginning with 2017, re-
24 duced expenditures attributable to
25 subparagraph (A) of subsection (b)(9)

1 and effective for fee schedules estab-
2 lished beginning with 2018, reduced
3 expenditures attributable to subpara-
4 graph (B) of such subsection.”.

5 (2) ELIMINATION OF APPLICATION OF MUL-
6 TIPLE PROCEDURE PAYMENT REDUCTION.—Section
7 1848(b)(4) of the Social Security Act (42 U.S.C.
8 1395w-4(b)(4)) is amended by adding at the end
9 the following new subparagraph:

10 “(E) ELIMINATION OF APPLICATION OF
11 MULTIPLE PROCEDURE PAYMENT REDUC-
12 TION.—

13 “(i) IN GENERAL.—Not later than
14 January 1, 2016, the Secretary shall not
15 apply a multiple procedure payment reduc-
16 tion policy to the professional component
17 of imaging services furnished in any subse-
18 quent year that is prior to a year in which
19 the Secretary conducts and publishes, as
20 part of the Medicare Physician Fee Sched-
21 ule Proposed Rule for a year, the empirical
22 analysis described in clause (ii).

23 “(ii) EMPIRICAL ANALYSIS DE-
24 SCRIBED.—The empirical analysis de-
25 scribed in this clause is an analysis of the

1 Resource-Based Relative Value Scale (com-
2 monly known as the ‘RBRVS’) Data Man-
3 ager information that is used to determine
4 what, if any, efficiencies exist within the
5 professional component of imaging services
6 when two or more studies are performed
7 on the same patient on the same day. Such
8 empirical analysis shall include—

9 “(I) work sheets and other infor-
10 mation detailing which physician work
11 activities performed given the typical
12 vignettes were assigned reduction per-
13 centages of 0, 25, 50, 75 and 100
14 percent;

15 “(II) a discussion of the clinical
16 aspects that informed the assignment
17 of the reduction percentages described
18 in subclause (I);

19 “(III) an explanation of how the
20 percentage reductions for pre-, intra
21 and post-service work were deter-
22 mined and calculated; and

23 “(IV) a demonstration that the
24 Centers for Medicare & Medicaid
25 Services has consulted with practicing

1 radiologists to gain knowledge of how
2 radiologists interpret studies of mul-
3 tiple body parts on the same indi-
4 vidual on the same day.”.

5 (b) PAYMENT INCENTIVE FOR TRANSITION UNDER
6 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYS-
7 TEM.—Section 1833(t)(16) of the Social Security Act (42
8 U.S.C. 1395(t)(16)) is amended by adding at the end the
9 following new subparagraph:

10 “(F) PAYMENT INCENTIVE FOR THE TRAN-
11 SITION FROM TRADITIONAL X-RAY IMAGING TO
12 DIGITAL RADIOGRAPHY.—Notwithstanding the
13 previous provisions of this subsection:

14 “(i) LIMITATION ON PAYMENT FOR
15 FILM X-RAY IMAGING SERVICES.—In the
16 case of imaging services that are X-rays
17 taken using film and that are furnished
18 during 2017 or a subsequent year, the pay-
19 ment amount for the technical component
20 (including the technical component portion
21 of a global fee) of such services that would
22 otherwise be determined under this section
23 (without application of this paragraph and
24 before application of any other adjustment

1 under this subsection) for such year shall
2 be reduced by 20 percent.

3 “(ii) PHASED-IN LIMITATION ON PAY-
4 MENT FOR COMPUTED RADIOGRAPHY IM-
5 AGING SERVICES.—In the case of imaging
6 services that are X-rays taken using com-
7 puted radiography technology (as defined
8 in section 1848(b)(9)(C))—

9 “(I) in the case of such services
10 furnished during 2018, 2019, 2020,
11 2021, or 2022 the payment amount
12 for the technical component (including
13 the technical component portion of a
14 global fee) of such services that would
15 otherwise be determined under this
16 section (without application of this
17 paragraph and before application of
18 any other adjustment under this sub-
19 section) for such year shall be reduced
20 by 7 percent; and

21 “(II) in the case of such services
22 furnished during 2023 or a subse-
23 quent year, the payment amount for
24 the technical component (including
25 the technical component portion of a

1 global fee) of such services that would
2 otherwise be determined under this
3 section (without application of this
4 paragraph and before application of
5 any other adjustment under this sub-
6 section) for such year shall be reduced
7 by 10 percent.

8 “(iii) APPLICATION WITHOUT REGARD
9 TO BUDGET NEUTRALITY.—The reductions
10 made under this paragraph—

11 “(I) shall not be considered an
12 adjustment under paragraph (2)(E);
13 and

14 “(II) shall not be implemented in
15 a budget neutral manner.”.

16 **SEC. 4003. IMPLEMENTATION OF OFFICE OF INSPECTOR**
17 **GENERAL RECOMMENDATION TO DELAY CER-**
18 **TAIN MEDICARE PRESCRIPTION DRUG PLAN**
19 **PREPAYMENTS.**

20 Section 1860D–15(d) of the Social Security Act (42
21 U.S.C. 1395w–115(d)) is amended by adding at the end
22 the following:

23 “(5) TIMING OF PAYMENTS.—With respect to
24 monthly reinsurance payment amounts under this
25 section to a PDP sponsor for months in a year (be-

1 ginning with 2020), such payment amounts for a
2 month shall be made on the first business day occur-
3 ring on or after the following date for that month:

4 “(A) For the month of January, January
5 2nd.

6 “(B) For the month of February, Feb-
7 ruary 5th.

8 “(C) For the month of March, March
9 10th.

10 “(D) For the month of April, April 15th.

11 “(E) For the month of May, May 20th.

12 “(F) For the month of June, June 25th.

13 “(G) For the month of July and each suc-
14 ceeding month (other than December) in a
15 year, the first day of the next month.

16 “(H) For the month of December, Decem-
17 ber 24th.”.

18 **Subtitle B—Cures Innovation Fund**

19 **SEC. 4041. CURES INNOVATION FUND.**

20 (a) ESTABLISHMENT.—There is hereby established in
21 the Treasury of the United States a fund to be known
22 as the Cures Innovation Fund (in this section referred to
23 as the “Fund”).

24 (b) APPROPRIATIONS.—There is hereby appropriated
25 to the Fund, out of any funds in the Treasury not other-

1 wise appropriated, \$110,000,000 for each of fiscal years
2 2016 through 2020.

3 (c) EXPENDITURES.—Amounts in the Fund shall be
4 available, as provided by appropriation Acts, for making
5 expenditures for carrying out the following:

6 (1) Section 229A of the Public Health Service
7 Act, as added by section 1123 (relating to data on
8 natural history of diseases).

9 (2) Part E of title II of the Public Health Serv-
10 ice Act, as added by section 1141 (relating to Coun-
11 cil for 21st Century Cures).

12 (3) Section 2001 and the amendments made by
13 such section (relating to development and use of pa-
14 tient experience data to enhance structured risk ben-
15 efit assessment framework).

16 (4) Section 2021 and the amendments made by
17 such section (relating to qualification of drug devel-
18 opment tools).

19 (5) Section 2062 and the amendments made by
20 such section (relating to utilizing evidence from clin-
21 ical experience).

22 (6) Section 2161 (relating to grants for study-
23 ing the process of continuous drug manufacturing).

1 (c) SUPPLEMENT, NOT SUPPLANT; PROHIBITION
2 AGAINST TRANSFER.—Funds appropriated by subsection

3 (b)—

4 (1) shall be used to supplement, not supplant,
5 amounts otherwise made available to the National
6 Institutes of Health and the Food and Drug Admin-
7 istration; and

8 (2) notwithstanding any transfer authority in
9 any appropriation Act, shall not be used for any
10 purpose other than the expenditures listed in sub-
11 section (c).

12 **Subtitle C—Other Reforms**

13 **SEC. 4061. SPR DRAWDOWN.**

14 (a) DRAWDOWN AND SALE.—Notwithstanding sec-
15 tion 161 of the Energy Policy and Conservation Act (42
16 U.S.C. 6241), the Secretary of Energy shall draw down
17 and sell 8,000,000 barrels of crude oil from the Strategic
18 Petroleum Reserve during each of the fiscal years 2018
19 through 2025, except as provided in subsection (b).

20 Amounts received for a sale under this subsection shall
21 be deposited in the General Fund of the Treasury during
22 the fiscal year in which the sale occurs.

23 (b) EMERGENCY PROTECTION.—The Secretary shall
24 not draw down and sell crude oil under this section in
25 amounts that would result in a Strategic Petroleum Re-

1 serve that contains an inventory of petroleum products
2 representing less than 90 days of emergency reserves,
3 based on the average daily level of net imports of crude
4 oil and petroleum products in the previous calendar year.

5 (c) PROCEEDS.—Proceeds from a sale under this sec-
6 tion shall be deposited into the general fund of the Treas-
7 ury of the United States.

8 **Subtitle D—Miscellaneous**

9 **SEC. 4081. LYME DISEASE AND OTHER TICK-BORNE DIS-** 10 **EASES.**

11 (a) IN GENERAL.—Title III of the Public Health
12 Service Act (42 U.S.C. 241 et seq.) is amended by adding
13 at the end the following new part:

14 **“PART W—LYME DISEASE AND OTHER TICK-** 15 **BORNE DISEASES**

16 **“SEC. 3990O. RESEARCH.**

17 “(a) IN GENERAL.—The Secretary shall conduct or
18 support epidemiological, basic, translational, and clinical
19 research regarding Lyme disease and other tick-borne dis-
20 eases.

21 “(b) BIENNIAL REPORTS.—The Secretary shall en-
22 sure that each biennial report under section 403 includes
23 information on actions undertaken by the National Insti-
24 tutes of Health to carry out subsection (a) with respect
25 to Lyme disease and other tick-borne diseases, including

1 an assessment of the progress made in improving the out-
2 comes of Lyme disease and such other tick-borne diseases.

3 **“SEC. 39900–1. WORKING GROUP.**

4 “(a) ESTABLISHMENT.—The Secretary shall estab-
5 lish a permanent working group, to be known as the Inter-
6 agency Lyme and Tick-Borne Disease Working Group (in
7 this section and section 39900–2 referred to as the
8 ‘Working Group’), to review all efforts within the Depart-
9 ment of Health and Human Services concerning Lyme dis-
10 ease and other tick-borne diseases to ensure interagency
11 coordination, minimize overlap, and examine research pri-
12 orities.

13 “(b) RESPONSIBILITIES.—The Working Group
14 shall—

15 “(1) not later than 24 months after the date of
16 enactment of this part, and every 24 months there-
17 after, develop or update a summary of—

18 “(A) ongoing Lyme disease and other tick-
19 borne disease research related to causes, pre-
20 vention, treatment, surveillance, diagnosis,
21 diagnostics, duration of illness, intervention,
22 and access to services and supports for individ-
23 uals with Lyme disease or other tick-borne dis-
24 eases;

1 “(B) advances made pursuant to such re-
2 search;

3 “(C) the engagement of the Department of
4 Health and Human Services with persons that
5 participate at the public meetings required by
6 paragraph (5); and

7 “(D) the comments received by the Work-
8 ing Group at such public meetings and the Sec-
9 retary’s response to such comments;

10 “(2) ensure that a broad spectrum of scientific
11 viewpoints is represented in each such summary;

12 “(3) monitor Federal activities with respect to
13 Lyme disease and other tick-borne diseases;

14 “(4) make recommendations to the Secretary
15 regarding any appropriate changes to such activities;
16 and

17 “(5) ensure public input by holding annual pub-
18 lic meetings that address scientific advances, re-
19 search questions, surveillance activities, and emerg-
20 ing strains in species of pathogenic organisms.

21 “(c) MEMBERSHIP.—

22 “(1) IN GENERAL.—The Working Group shall
23 be composed of a total of 14 members as follows:

1 “(A) FEDERAL MEMBERS.—Seven Federal
2 members, consisting of one or more representa-
3 tives of each of—

4 “(i) the Office of the Assistant Sec-
5 retary for Health;

6 “(ii) the Food and Drug Administra-
7 tion;

8 “(iii) the Centers for Disease Control
9 and Prevention;

10 “(iv) the National Institutes of
11 Health; and

12 “(v) such other agencies and offices of
13 the Department of Health and Human
14 Services as the Secretary determines ap-
15 propriate.

16 “(B) NON-FEDERAL PUBLIC MEMBERS.—
17 Seven non-Federal public members, consisting
18 of representatives of the following categories:

19 “(i) Physicians and other medical pro-
20 viders with experience in diagnosing and
21 treating Lyme disease and other tick-borne
22 diseases.

23 “(ii) Scientists or researchers with ex-
24 pertise.

1 “(iii) Patients and their family mem-
2 bers.

3 “(iv) Nonprofit organizations that ad-
4 vocate for patients with respect to Lyme
5 disease and other tick-borne diseases.

6 “(v) Other individuals whose expertise
7 is determined by the Secretary to be bene-
8 ficial to the functioning of the Working
9 Group.

10 “(2) APPOINTMENT.—The members of the
11 Working Group shall be appointed by the Secretary,
12 except that of the non-Federal public members
13 under paragraph (1)(B)—

14 “(A) one shall be appointed by the Speaker
15 of the House of Representatives; and

16 “(B) one shall be appointed by the Major-
17 ity Leader of the Senate.

18 “(3) DIVERSITY OF SCIENTIFIC PERSPEC-
19 TIVES.—In making appointments under paragraph
20 (2), the Secretary, the Speaker of the House of Rep-
21 resentatives, and the Majority Leader of the Senate
22 shall ensure that the non-Federal public members of
23 the Working Group represent a diversity of scientific
24 perspectives.

1 “(4) TERMS.—The non-Federal public members
2 of the Working Group shall each be appointed to
3 serve a 4-year term and may be reappointed at the
4 end of such term.

5 “(d) MEETINGS.—The Working Group shall meet as
6 often as necessary, as determined by the Secretary, but
7 not less than twice each year.

8 “(e) APPLICABILITY OF FACCA.—The Working Group
9 shall be treated as an advisory committee subject to the
10 Federal Advisory Committee Act.

11 “(f) REPORTING.—Not later than 24 months after
12 the date of enactment of this part, and every 24 months
13 thereafter, the Working Group—

14 “(1) shall submit a report on its activities, in-
15 cluding an up-to-date summary under subsection
16 (b)(1) and any recommendations under subsection
17 (b)(4), to the Secretary, the Committee on Energy
18 and Commerce of the House of Representatives, and
19 the Committee on Health, Education, Labor and
20 Pensions of the Senate;

21 “(2) shall make each such report publicly avail-
22 able on the website of the Department of Health and
23 Human Services; and

24 “(3) shall allow any member of the Working
25 Group to include in any such report minority views.

1 **“SEC. 39900–2. STRATEGIC PLAN.**

2 “Not later than 3 years after the date of enactment
3 of this section, and every 5 years thereafter, the Secretary
4 shall submit to the Congress a strategic plan, informed
5 by the most recent summary under section 39900–
6 1(b)(1), for the conduct and support of Lyme disease and
7 tick-borne disease research, including—

8 “(1) proposed budgetary requirements;

9 “(2) a plan for improving outcomes of Lyme
10 disease and other tick-borne diseases, including
11 progress related to chronic or persistent symptoms
12 and chronic or persistent infection and co-infections;

13 “(3) a plan for improving diagnosis, treatment,
14 and prevention;

15 “(4) appropriate benchmarks to measure
16 progress on achieving the improvements described in
17 paragraphs (2) and (3); and

18 “(5) a plan to disseminate each summary under
19 section 39900–1(b)(1) and other relevant informa-
20 tion developed by the Working Group to the public,
21 including health care providers, public health depart-
22 ments, and other relevant medical groups.”.

23 (b) NO ADDITIONAL AUTHORIZATION OF APPRO-
24 PRIATIONS.—No additional funds are authorized to be ap-
25 propriated for the purpose of carrying out this section and
26 the amendment made by this section, and this section and

- 1 such amendment shall be carried out using amounts other-
- 2 wise available for such purpose.

