

Calendar No. 427

114TH CONGRESS
2D SESSION

S. 2700

To update the authorizing provisions relating to the workforces of the National Institutes of Health and the Food and Drug Administration, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 17, 2016

Mr. ALEXANDER (for himself and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 18, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To update the authorizing provisions relating to the workforces of the National Institutes of Health and the Food and Drug Administration, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA and NIH Work-
5 force Authorities Modernization Act”.

1 **SEC. 2. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH**
 2 **SERVICE.**

3 (a) **HIRING AND RETENTION AUTHORITY.**—Section
 4 228 of the Public Health Service Act (42 U.S.C. 237) is
 5 amended—

6 (1) in the section heading, by inserting “**AND**
 7 **BIOMEDICAL PRODUCT ASSESSMENT**” after “**RE-**
 8 **SEARCH**”;

9 (2) in subsection (a)—

10 (A) in paragraph (1), by striking “**Silvio**
 11 **O. Conte Senior Biomedical Research Service,**
 12 **not to exceed 500 members**” and inserting
 13 “**Silvio O. Conte Senior Biomedical Research**
 14 **and Biomedical Product Assessment Service (in**
 15 **this section referred to as the ‘Service’), not to**
 16 **exceed 2,000 members, the purpose of which is**
 17 **to recruit and retain outstanding and qualified**
 18 **scientific and technical experts in the fields of**
 19 **biomedical research, clinical research evalua-**
 20 **tion, and biomedical product assessment**”;

21 (B) by amending paragraph (2) to read as
 22 follows:

23 “(2) The authority established in paragraph (1) may
 24 not be construed to require the Secretary to reduce the
 25 number of employees serving under any other employment

1 system in order to offset the number of members serving
2 in the Service.”; and

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

4 “(3) The Secretary shall assign experts under this
5 section to agencies within the Department of Health and
6 Human Services taking into account the need for the ex-
7 pertise of such expert.”;

8 (3) in subsection (b)—

9 (A) in the matter preceding paragraph (1),
10 by striking “or clinical research evaluation” and
11 inserting “; clinical research evaluation; or bio-
12 medical product assessment”; and

13 (B) in paragraph (1), by inserting “or a
14 doctoral or master’s level degree in engineering;
15 bioinformatics; or a related or emerging field,”
16 after the comma;

17 (4) in subsection (d)(2), by striking “and shall
18 not exceed the rate payable for level I of the Execu-
19 tive Schedule unless approved by the President
20 under section 5377(d)(2) of title 5, United States
21 Code” and inserting “and shall not exceed the
22 amount of annual compensation (excluding expenses)
23 specified in section 102 of title 3, United States
24 Code”;

25 (5) by striking subsection (e); and

1 (6) by redesignating subsections (f) and (g) as
2 subsections (e) and (f), respectively.

3 (b) GAO STUDY.—

4 (1) IN GENERAL.—The Comptroller General of
5 the United States shall conduct a study of the effec-
6 tiveness of the amendments to section 228 of the
7 Public Health Service Act (42 U.S.C. 237) made by
8 subsection (a) and the impact of such amendments,
9 if any, on all agencies or departments of the Depart-
10 ment of Health and Human Services, and, not later
11 than 4 years after the date of enactment of this Act,
12 shall submit a report based on such study to the
13 Committee on Health, Education, Labor, and Pen-
14 sions of the Senate and the Committee on Energy
15 and Commerce of the House of Representatives.

16 (2) CONTENT OF STUDY AND REPORT.—The
17 study and report under paragraph (1) shall include
18 an examination of the extent to which recruitment
19 and retention of outstanding and qualified scientific,
20 medical, or technical experts in the fields of bio-
21 medical research, clinical research evaluation, and
22 biomedical product assessment has improved or oth-
23 erwise has been affected by the amendments to sec-
24 tion 228 of the Public Health Service Act (42
25 U.S.C. 237) made by subsection (a), including by

1 determining, during the period between the date of
2 enactment of this Act and the completion of the
3 study—

4 (A) the total number of members recruited
5 and retained under the Senior Biomedical Re-
6 search and Biomedical Product Assessment
7 Service under such section 228, and the effect
8 of increasing the number of members eligible
9 for such Service;

10 (B) the number of members of such Senior
11 Biomedical Research and Biomedical Product
12 Assessment Service hired with a doctoral level
13 degree in biomedicine or a related field, or doc-
14 toral or master's level degree in engineering,
15 bioinformatics, or a related or emerging field;
16 and

17 (C) how many Senior Biomedical Research
18 and Biomedical Product Assessment Service
19 members have been hired by each agency or de-
20 partment of the Department of Health and
21 Human Services, and how such Department as-
22 signs such members to each agency or depart-
23 ment.

1 **SEC. 3. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL,**
 2 **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. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**
 7 **NICAL, AND PROFESSIONAL PERSONNEL.**

8 “(a) **IN GENERAL.**—The Secretary may, without re-
 9 gard to the provisions of title 5, United States Code, gov-
 10 erning appointments in the competitive service, appoint
 11 outstanding and qualified candidates to scientific, tech-
 12 nical, or professional positions that support the develop-
 13 ment, review, and regulation of medical products. Such po-
 14 sitions shall be within the competitive service.

15 “(b) **COMPENSATION.**—

16 “(1) **IN GENERAL.**—Notwithstanding any other
 17 provision of law, including any requirement with re-
 18 spect to General Schedule pay rates under sub-
 19 chapter III of chapter 53 of title 5, United States
 20 Code, and consistent with the requirements of para-
 21 graph (2), the Commissioner of Food and Drugs
 22 may determine and fix—

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

25 “(B) for purposes of retaining qualified
 26 employees, the annual rate of pay for any quali-

1 fied scientific, technical, or professional per-
2 sonnel appointed to a position described in sub-
3 section (a) before the date of enactment of this
4 section.

5 “(2) LIMITATION.—The annual rate of pay es-
6 tablished pursuant to paragraph (1) may not exceed
7 the amount of annual compensation (excluding ex-
8 penses) specified in section 102 of title 3, United
9 States Code.

10 “(3) PUBLIC AVAILABILITY.—The annual rate
11 of pay provided to an individual in accordance with
12 this section shall be publicly available information.

13 “(c) RULE OF CONSTRUCTION.—The authorities
14 under this section shall not be construed to affect the au-
15 thority provided under section 714.

16 “(d) REPORT ON WORKFORCE PLANNING.—

17 “(1) IN GENERAL.—Not later than 18 months
18 after the date of enactment of the FDA and NIH
19 Workforce Authorities Modernization Act, the Sec-
20 retary shall submit a report on workforce planning
21 to the Committee on Health, Education, Labor, and
22 Pensions of the Senate and the Committee on En-
23 ergy and Commerce of the House of Representatives
24 that examines the extent to which the Food and
25 Drug Administration has a critical need for qualified

1 individuals for scientific, technical, or professional
2 positions, including—

3 “(A) an analysis of the workforce needs at
4 the Food and Drug Administration and the
5 Secretary’s strategic plan for addressing such
6 needs, including through use of the authority
7 under this section; and

8 “(B) a recruitment and retention plan for
9 hiring qualified scientific, technical, and profes-
10 sional candidates, which may include the use
11 of—

12 “(i) recruitment through non-govern-
13 mental recruitment or placement agencies;

14 “(ii) recruitment through academic in-
15 stitutions;

16 “(iii) recruitment or hiring bonuses, if
17 applicable;

18 “(iv) recruitment using targeted direct
19 hiring authorities; and

20 “(v) retention of qualified scientific,
21 technical, and professional employees using
22 the authority under this section, or other
23 applicable authorities of the Secretary.

24 “(2) RECOMMENDATIONS.—The report under
25 paragraph (1) may include the recommendations of

1 the Commissioner of Food and Drugs that would
2 help the Food and Drug Administration to better re-
3 cruit and retain qualified individuals for scientific,
4 technical, or professional positions at the agency.”.

5 (b) GAO STUDY AND REPORT.—

6 (1) IN GENERAL.—The Comptroller General of
7 the United States shall conduct a study of the abil-
8 ity of the Food and Drug Administration to hire,
9 train, and retain qualified scientific, technical, and
10 professional staff, not including contractors, nec-
11 essary to fulfill the mission of the Food and Drug
12 Administration to protect and promote public health.
13 Not later than January 1, 2022, the Comptroller
14 General shall submit a report on such study to the
15 Committee on Health, Education, Labor, and Pen-
16 sions of the Senate and the Committee on Energy
17 and Commerce of the House of Representatives.

18 (2) CONTENTS OF STUDY.—The Comptroller
19 General shall include in the study and report under
20 paragraph (1)—

21 (A) information about the progress of the
22 Food and Drug Administration in recruiting
23 and retaining qualified scientific, technical, and
24 professional staff outstanding in the field of

1 biomedical research, clinical research evalua-
 2 tion, and biomedical product assessment;

3 (B) the extent to which critical staffing
 4 needs exist at the Food and Drug Administra-
 5 tion, and barriers to hiring, training, and re-
 6 taining qualified staff, if any;

7 (C) an examination of the recruitment and
 8 retention strategies of the Food and Drug Ad-
 9 ministration, including examining any strategic
 10 workforce plan, focused on improving scientific,
 11 technical, and professional staff recruitment
 12 and retention; and

13 (D) recommendations for potential im-
 14 provements that would address staffing needs
 15 of the Food and Drug Administration.

16 **SEC. 4. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRA-**
 17 **TION INTERCENTER INSTITUTES.**

18 (a) IN GENERAL.—Chapter X of the Federal Food,
 19 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
 20 ed by adding at the end the following:

21 **“SEC. 1014. FOOD AND DRUG ADMINISTRATION INTER-**
 22 **CENTER INSTITUTES.**

23 “(a) IN GENERAL.—The Secretary shall establish one
 24 or more Intercenter Institutes within the Food and Drug
 25 Administration (referred to in this section as an ‘Insti-

1 tute’) for a major disease area or areas. With respect to
2 the major disease area of focus of an Institute, such Insti-
3 tute shall develop and implement processes for coordina-
4 tion of activities, as applicable to such major disease area
5 or areas, between the Center for Drug Evaluation and Re-
6 search, the Center for Biologics Evaluation and Research,
7 and the Center for Devices and Radiological Health (for
8 the purposes of this section, referred to as the ‘Centers’).
9 Such activities may include—

10 “(1) coordination of staff from the Centers with
11 diverse product expertise in the diagnosis, cure, miti-
12 gation, treatment, or prevention of the specific dis-
13 eases relevant to the major disease area of focus of
14 the Institute;

15 “(2) streamlining, where appropriate, the re-
16 view of medical products to diagnose, cure, mitigate,
17 treat, or prevent the major disease area of focus of
18 the Institute, applying relevant standards under sec-
19 tions 505, 510(k), and 515 of this Act and section
20 351 of the Public Health Service Act, and other ap-
21 plicable authorities;

22 “(3) promotion of scientific programs within
23 the Centers related to the major disease area of
24 focus of the Institute;

1 “(4) development of programs and enhancement
2 of strategies to recruit, train, and provide continuing
3 education opportunities for the personnel of the Cen-
4 ters with expertise related to the major disease area
5 of focus of the Institute;

6 “(5) enhancement of the interactions of the
7 Centers with patients, sponsors, and the external
8 biomedical community regarding the major disease
9 area of focus of the Institute; and

10 “(6) facilitation of the collaborative relation-
11 ships of the Centers with other agencies within the
12 Department of Health and Human Services regard-
13 ing the major disease area of focus of the Institute.

14 “(b) IMPLEMENTATION PLAN.—Prior to establishing
15 an Institute under subsection (a), and not later than 1
16 year after the date of enactment of the FDA and NIH
17 Workforce Authorities Modernization Act, the Secretary
18 shall publish a draft implementation plan for such Insti-
19 tute, and provide for not less than 60 calendar days for
20 public comment on such plan.

21 “(c) TIMING.—The Secretary shall establish at least
22 one Institute under subsection (a) within 1 year of the
23 closing of the public comment period under subsection (b),
24 unless the Secretary determines that establishing such In-
25 stitute would not be feasible or would not benefit the pub-

1 lie health, and publishes such determination on the public
2 Internet website of the Food and Drug Administration.

3 “(d) **TERMINATION OF INSTITUTES.**—The Secretary
4 may terminate any Institute established pursuant to this
5 section if the Secretary determines such Institute is no
6 longer benefitting the public health. Not less than 60 days
7 prior to so terminating an Institute, the Secretary shall
8 provide public notice, including the rationale for such ter-
9 mination.”.

10 (b) **TECHNICAL AMENDMENTS.**—Chapter X of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391
12 et seq.) is amended—

13 (1) by redesignating section 1012 as section
14 1013; and

15 (2) by redesignating the second section 1011
16 (with respect to improving the training of State,
17 local, territorial, and tribal food safety officials), as
18 added by section 209(a) of the FDA Food Safety
19 Modernization Act (Public Law 111–353), as section
20 1012.

21 **SEC. 5. SCIENTIFIC MEETINGS.**

22 (a) **IN GENERAL.**—Scientific meetings that are at-
23 tended by scientific or medical personnel, or other profes-
24 sionals, of the Department of Health and Human Services
25 for whom attendance at such meeting is directly related

1 to their professional duties and the mission of the Depart-
2 ment—

3 (1) shall not be considered conferences for the
4 purposes of complying with Federal reporting re-
5 quirements contained in annual appropriations Acts
6 or in this section; and

7 (2) shall not be considered conferences for pur-
8 poses of a restriction contained in an annual appro-
9 priations Act, based on Office of Management and
10 Budget Memorandum M-12-12 or any other regula-
11 tion restricting such travel.

12 (b) LIMITATION.—Nothing in this section shall be
13 construed to exempt travel for scientific meetings from
14 Federal regulations relating to travel.

15 (c) REPORTS.—Each operating division of the De-
16 partment of Health and Human Services shall prepare,
17 and post on an Internet website of the operating division,
18 an annual report on scientific meeting attendance and re-
19 lated travel spending for each fiscal year. Such report shall
20 include—

21 (1) general information concerning the scientific
22 meeting activities involved;

23 (2) information concerning the total amount ex-
24 pended for such meetings;

1 ~~(3)~~ a description of all such meetings that were
 2 attended by scientific or medical personnel, or other
 3 professionals, of each such operating division where
 4 the total amount expended by the operating division
 5 associated with each such meeting are in excess of
 6 \$30,000, including—

7 (A) the total amount of meeting expenses
 8 incurred by the operating division for such
 9 meeting;

10 (B) the location of such meeting;

11 (C) the date of such meeting;

12 (D) a brief explanation on how such meet-
 13 ing advanced the mission of the operating divi-
 14 sion; and

15 (E) the total number of individuals whose
 16 travel expenses or other scientific meeting ex-
 17 penses were paid by the operating division; and

18 ~~(4)~~ with respect to any such meeting where the
 19 total expenses to the operating division exceeded
 20 \$150,000, a description of the exceptional cir-
 21 cumstances that necessitated the expenditure of such
 22 amounts.

23 **SEC. 6. REAGAN-UDALL FOUNDATION FOR THE FOOD AND**
 24 **DRUG ADMINISTRATION.**

25 (a) BOARD OF DIRECTORS.—

1 (1) COMPOSITION AND SIZE.—Section
2 770(d)(1)(C) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

4 (A) by redesignating clause (ii) as clause

5 (iii);

6 (B) by inserting after clause (i) the fol-

7 lowing:

8 “(ii) ADDITIONAL MEMBERS.—The

9 Board, through amendments to the bylaws

10 of the Foundation, may provide that the

11 number of voting members of the Board

12 shall be a number (to be specified in such

13 amendment) greater than 14. Any Board

14 positions that are established by any such

15 amendment shall be appointed (by majority

16 vote) by the individuals who, as of the date

17 of such amendment, are voting members of

18 the Board and persons so appointed may

19 represent any of the categories specified in

20 subclauses (I) through (V) of clause (i), so

21 long as no more than 30 percent of the

22 total voting members of the Board (includ-

23 ing members whose positions are estab-

24 lished by such amendment) are representa-

25 tives of the general pharmaceutical, device,

1 food, cosmetic, and biotechnology indus-
 2 tries.”; and

3 (C) in clause (iii)(I), as redesignated by
 4 subparagraph (A), by striking “The ex officio
 5 members shall ensure” and inserting “The ex
 6 officio members, acting pursuant to clause (i),
 7 and the Board, acting pursuant to clause (ii),
 8 shall ensure”.

9 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE
 10 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)
 11 of the Federal Food, Drug, and Cosmetic Act (21
 12 U.S.C. 379dd(d)(1)(C)), as redesignated by para-
 13 graph (1)(A), is amended by adding at the end the
 14 following: “For purposes of this section, the term
 15 ‘employee of the Federal Government’ does not in-
 16 clude a ‘special Government employee’, as that term
 17 is defined in section 202(a) of title 18, United
 18 States Code.”.

19 (3) STAGGERED TERMS.—Subparagraph (A) of
 20 section 770(d)(3) of the Federal Food, Drug, and
 21 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended
 22 to read as follows:

23 “(A) TERM.—The term of office of each
 24 member of the Board appointed under para-
 25 graph (1)(C)(i), and the term of office of any

1 member of the Board whose position is estab-
2 lished pursuant to paragraph (1)(C)(ii), shall be
3 4 years, except that—

4 “(i) the terms of offices for the mem-
5 bers of the Board initially appointed under
6 paragraph (1)(C)(i) shall expire on a stag-
7 gered basis as determined by the ex officio
8 members; and

9 “(ii) the terms of office for the per-
10 sons initially appointed to positions estab-
11 lished pursuant to paragraph (1)(C)(ii)
12 may be made to expire on a staggered
13 basis, as determined by the individuals
14 who, as of the date of the amendment es-
15 tablishing such positions, are members of
16 the Board.”.

17 (b) EXECUTIVE DIRECTOR COMPENSATION.—Section
18 770(g)(2) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall
20 not be greater than the compensation of the Commis-
21 sioner”.

22 (c) SEPARATION OF FUNDS.—Section 770(m) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379dd(m)) is amended by striking “are held in separate
25 accounts from funds received from entities under sub-

1 section (i)” and inserting “are managed as individual pro-
 2 grammatic funds under subsection (i), according to best
 3 accounting practices”.

4 **SEC. 7. NIH RESEARCH INFORMATION COLLECTION EX-**
 5 **EMPTED FROM PAPERWORK REDUCTION**
 6 **ACT.**

7 Section 301 of the Public Health Service Act (42
 8 U.S.C. 241) is amended by adding to the end the fol-
 9 lowing:

10 “(f) PAPERWORK REDUCTION.—Subchapter I of
 11 chapter 35 of title 44, United States Code, shall not apply
 12 to the collection of information during the conduct of re-
 13 search by the National Institutes of Health.”.

14 **SEC. 8. STUDIES.**

15 The Federal Food, Drug, and Cosmetic Act is amend-
 16 ed—

17 (1) in section 505(k)(5) (21 U.S.C.
 18 355(k)(5))—

19 (A) in subparagraph (A), by inserting
 20 “and” after the semicolon;

21 (B) by striking subparagraph (B); and

22 (C) by redesignating subparagraph (C) as
 23 subparagraph (B);

24 (2) in section 505A (21 U.S.C. 355a), by strik-
 25 ing subsection (p);

1 ~~(3) in section 505B (21 U.S.C. 355c)—~~
 2 ~~(A) by striking subsection (l); and~~
 3 ~~(B) by redesignating subsection (m) as~~
 4 ~~subsection (l); and~~
 5 ~~(4) in section 523 (21 U.S.C. 360m), by strik-~~
 6 ~~ing subsection (d).~~

7 **SECTION 1. SHORT TITLE.**

8 *This Act may be cited as the “FDA and NIH Work-*
 9 *force Authorities Modernization Act”.*

10 **SEC. 2. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH**
 11 **SERVICE.**

12 *(a) HIRING AND RETENTION AUTHORITY.—Section*
 13 *228 of the Public Health Service Act (42 U.S.C. 237) is*
 14 *amended—*

15 *(1) in the section heading, by inserting “AND*
 16 *BIOMEDICAL PRODUCT ASSESSMENT” after “RE-*
 17 *SEARCH”;*

18 *(2) in subsection (a)—*

19 *(A) in paragraph (1), by striking “Silvio O.*
 20 *Conte Senior Biomedical Research Service, not*
 21 *to exceed 500 members” and inserting “Silvio O.*
 22 *Conte Senior Biomedical Research and Bio-*
 23 *medical Product Assessment Service (in this sec-*
 24 *tion referred to as the ‘Service’), not to exceed*
 25 *2,000 members, the purpose of which is to recruit*

1 *and retain outstanding and qualified scientific*
2 *and technical experts in the fields of biomedical*
3 *research, clinical research evaluation, and bio-*
4 *medical product assessment”;*

5 *(B) by amending paragraph (2) to read as*
6 *follows:*

7 “(2) *The authority established in paragraph (1) may*
8 *not be construed to require the Secretary to reduce the num-*
9 *ber of employees serving under any other employment sys-*
10 *tem in order to offset the number of members serving in*
11 *the Service.”; and*

12 *(C) by adding at the end the following:*

13 “(3) *The Secretary shall assign experts under this sec-*
14 *tion to agencies within the Department of Health and*
15 *Human Services taking into account the need for the exper-*
16 *tise of such expert.”;*

17 *(3) in subsection (b)—*

18 *(A) in the matter preceding paragraph (1),*
19 *by striking “or clinical research evaluation” and*
20 *inserting “, clinical research evaluation, or bio-*
21 *medical product assessment”;* and

22 *(B) in paragraph (1), by inserting “or a*
23 *doctoral or master’s level degree in engineering,*
24 *bioinformatics, or a related or emerging field,”*
25 *after the comma;*

1 (4) *in subsection (d)(2), by striking “and shall*
2 *not exceed the rate payable for level I of the Executive*
3 *Schedule unless approved by the President under sec-*
4 *tion 5377(d)(2) of title 5, United States Code” and*
5 *inserting “and shall not exceed the amount of annual*
6 *compensation (excluding expenses) specified in section*
7 *102 of title 3, United States Code”;*

8 (5) *by striking subsection (e); and*

9 (6) *by redesignating subsections (f) and (g) as*
10 *subsections (e) and (f), respectively.*

11 *(b) GAO STUDY.—*

12 (1) *IN GENERAL.—The Comptroller General of*
13 *the United States shall conduct a study of the effec-*
14 *tiveness of the amendments to section 228 of the Pub-*
15 *lic Health Service Act (42 U.S.C. 237) made by sub-*
16 *section (a) and the impact of such amendments, if*
17 *any, on all agencies or departments of the Depart-*
18 *ment of Health and Human Services, and, not later*
19 *than 4 years after the date of enactment of this Act,*
20 *shall submit a report based on such study to the Com-*
21 *mittee on Health, Education, Labor, and Pensions of*
22 *the Senate and the Committee on Energy and Com-*
23 *merce of the House of Representatives.*

24 (2) *CONTENT OF STUDY AND REPORT.—The*
25 *study and report under paragraph (1) shall include*

1 *an examination of the extent to which recruitment*
2 *and retention of outstanding and qualified scientific,*
3 *medical, or technical experts in the fields of bio-*
4 *medical research, clinical research evaluation, and*
5 *biomedical product assessment has improved or other-*
6 *wise has been affected by the amendments to section*
7 *228 of the Public Health Service Act (42 U.S.C. 237)*
8 *made by subsection (a), including by determining,*
9 *during the period between the date of enactment of*
10 *this Act and the completion of the study—*

11 *(A) the total number of members recruited*
12 *and retained under the Senior Biomedical Re-*
13 *search and Biomedical Product Assessment Serv-*
14 *ice under such section 228, and the effect of in-*
15 *creasing the number of members eligible for such*
16 *Service;*

17 *(B) the number of members of such Senior*
18 *Biomedical Research and Biomedical Product*
19 *Assessment Service hired with a doctoral level*
20 *degree in biomedicine or a related field, or doc-*
21 *toral or master's level degree in engineering,*
22 *bioinformatics, or a related or emerging field;*
23 *and*

24 *(C) how many Senior Biomedical Research*
25 *and Biomedical Product Assessment Service*

1 *members have been hired by each agency or de-*
 2 *partment of the Department of Health and*
 3 *Human Services, and how such Department as-*
 4 *signs such members to each agency or depart-*
 5 *ment.*

6 **SEC. 3. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL,**
 7 **AND PROFESSIONAL PERSONNEL.**

8 *(a) IN GENERAL.—The Federal Food, Drug, and Cos-*
 9 *metic Act is amended by inserting after section 714 (21*
 10 *U.S.C. 379d–3) the following:*

11 **“SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECH-**
 12 **NICAL, AND PROFESSIONAL PERSONNEL.**

13 *“(a) IN GENERAL.—The Secretary may, without re-*
 14 *gard to the provisions of title 5, United States Code, gov-*
 15 *erning appointments in the competitive service, appoint*
 16 *outstanding and qualified candidates to scientific, tech-*
 17 *nical, or professional positions that support the develop-*
 18 *ment, review, and regulation of medical products. Such po-*
 19 *sitions 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 subchapter*
 24 *III of chapter 53 of title 5, United States Code, and*
 25 *consistent with the requirements of paragraph (2), the*

1 *Commissioner of Food and Drugs may determine and*
2 *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 em-*
6 *ployees, the annual rate of pay for any qualified*
7 *scientific, technical, or professional personnel ap-*
8 *pointed to a position described in subsection (a)*
9 *before the date of enactment of this section.*

10 *“(2) LIMITATION.—The annual rate of pay es-*
11 *tablished pursuant to paragraph (1) may not exceed*
12 *the amount of annual compensation (excluding ex-*
13 *penses) specified in section 102 of title 3, United*
14 *States Code.*

15 *“(3) PUBLIC AVAILABILITY.—The annual rate of*
16 *pay provided to an individual in accordance with*
17 *this section shall be publicly available information.*

18 *“(c) RULE OF CONSTRUCTION.—The authorities under*
19 *this section shall not be construed to affect the authority*
20 *provided under section 714.*

21 *“(d) REPORT ON WORKFORCE PLANNING.—*

22 *“(1) IN GENERAL.—Not later than 18 months*
23 *after the date of enactment of the FDA and NIH*
24 *Workforce Authorities Modernization Act , the Sec-*
25 *retary shall submit a report on workforce planning to*

1 *the Committee on Health, Education, Labor, and*
2 *Pensions of the Senate and the Committee on Energy*
3 *and Commerce of the House of Representatives that*
4 *examines the extent to which the Food and Drug Ad-*
5 *ministration has a critical need for qualified individ-*
6 *uals for scientific, technical, or professional positions,*
7 *including—*

8 *“(A) an analysis of the workforce needs at*
9 *the Food and Drug Administration and the Sec-*
10 *retary’s strategic plan for addressing such needs,*
11 *including through use of the authority under this*
12 *section; and*

13 *“(B) a recruitment and retention plan for*
14 *hiring qualified scientific, technical, and profes-*
15 *sional candidates, which may include the use*
16 *of—*

17 *“(i) recruitment through non-govern-*
18 *mental recruitment or placement agencies;*

19 *“(ii) recruitment through academic in-*
20 *stitutions;*

21 *“(iii) recruitment or hiring bonuses, if*
22 *applicable;*

23 *“(iv) recruitment using targeted direct*
24 *hiring authorities; and*

1 “(v) retention of qualified scientific,
2 technical, and professional employees using
3 the authority under this section, or other
4 applicable authorities of the Secretary.

5 “(2) *RECOMMENDATIONS.*—*The report under*
6 *paragraph (1) may include the recommendations of*
7 *the Commissioner of Food and Drugs that would help*
8 *the Food and Drug Administration to better recruit*
9 *and retain qualified individuals for scientific, tech-*
10 *nical, or professional positions at the agency.”.*

11 **(b) GAO STUDY AND REPORT.**—

12 **(1) IN GENERAL.**—*The Comptroller General of*
13 *the United States shall conduct a study of the ability*
14 *of the Food and Drug Administration to hire, train,*
15 *and retain qualified scientific, technical, and profes-*
16 *sional staff, not including contractors, necessary to*
17 *fulfill the mission of the Food and Drug Administra-*
18 *tion to protect and promote public health. Not later*
19 *than January 1, 2022, the Comptroller General shall*
20 *submit a report on such study to the Committee on*
21 *Health, Education, Labor, and Pensions of the Senate*
22 *and the Committee on Energy and Commerce of the*
23 *House of Representatives.*

1 (2) *CONTENTS OF STUDY.*—*The Comptroller*
2 *General shall include in the study and report under*
3 *paragraph (1)—*

4 (A) *information about the progress of the*
5 *Food and Drug Administration in recruiting*
6 *and retaining qualified scientific, technical, and*
7 *professional staff outstanding in the field of bio-*
8 *medical research, clinical research evaluation,*
9 *and biomedical product assessment;*

10 (B) *the extent to which critical staffing*
11 *needs exist at the Food and Drug Administra-*
12 *tion, and barriers to hiring, training, and re-*
13 *taining qualified staff, if any;*

14 (C) *an examination of the recruitment and*
15 *retention strategies of the Food and Drug Ad-*
16 *ministration, including examining any strategic*
17 *workforce plan, focused on improving scientific,*
18 *technical, and professional staff recruitment and*
19 *retention; and*

20 (D) *recommendations for potential improve-*
21 *ments that would address staffing needs of the*
22 *Food and Drug Administration.*

1 **SEC. 4. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRA-**
 2 **TION INTERCENTER INSTITUTES.**

3 (a) *IN GENERAL.*—Chapter X of the Federal Food,
 4 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended
 5 by adding at the end the following:

6 **“SEC. 1014. FOOD AND DRUG ADMINISTRATION INTER-**
 7 **CENTER INSTITUTES.**

8 “(a) *IN GENERAL.*—The Secretary shall establish one
 9 or more Intercenter Institutes within the Food and Drug
 10 Administration (referred to in this section as an ‘Institute’)
 11 for a major disease area or areas. With respect to the major
 12 disease area of focus of an Institute, such Institute shall
 13 develop and implement processes for coordination of activi-
 14 ties, as applicable to such major disease area or areas, be-
 15 tween the Center for Drug Evaluation and Research, the
 16 Center for Biologics Evaluation and Research, and the Cen-
 17 ter for Devices and Radiological Health (for the purposes
 18 of this section, referred to as the ‘Centers’). Such activities
 19 may include—

20 “(1) coordination of staff from the Centers with
 21 diverse product expertise in the diagnosis, cure, miti-
 22 gation, treatment, or prevention of the specific dis-
 23 eases relevant to the major disease area of focus of the
 24 Institute;

25 “(2) streamlining, where appropriate, the review
 26 of medical products to diagnose, cure, mitigate, treat,

1 or prevent the major disease area of focus of the Insti-
2 tute, applying relevant standards under sections 505,
3 510(k), 513(f)(2), and 515 of this Act and section 351
4 of the Public Health Service Act, and other applicable
5 authorities;

6 “(3) promotion of scientific programs within the
7 Centers related to the major disease area of focus of
8 the Institute;

9 “(4) development of programs and enhancement
10 of strategies to recruit, train, and provide continuing
11 education opportunities for the personnel of the Cen-
12 ters with expertise related to the major disease area
13 of focus of the Institute;

14 “(5) enhancement of the interactions of the Cen-
15 ters with patients, sponsors, and the external bio-
16 medical community regarding the major disease area
17 of focus of the Institute; and

18 “(6) facilitation of the collaborative relationships
19 of the Centers with other agencies within the Depart-
20 ment of Health and Human Services regarding the
21 major disease area of focus of the Institute.

22 “(b) PUBLIC PROCESS.—The Secretary shall provide
23 a period for public comment during the time that each In-
24 stitute is being implemented.

1 “(c) *TIMING.*—*The Secretary shall establish at least*
2 *one Institute under subsection (a) before the date that is*
3 *1 year after the date of enactment of the FDA and NIH*
4 *Workforce Authorities Modernization Act.*

5 “(d) *TERMINATION OF INSTITUTES.*—*The Secretary*
6 *may terminate any Institute established pursuant to this*
7 *section if the Secretary determines such Institute is no*
8 *longer benefitting the public health. Not less than 60 days*
9 *prior to so terminating an Institute, the Secretary shall*
10 *provide public notice, including the rationale for such ter-*
11 *mination.”.*

12 (b) *TECHNICAL AMENDMENTS.*—*Chapter X of the Fed-*
13 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.)*
14 *is amended—*

15 (1) *by redesignating section 1012 as section*
16 *1013; and*

17 (2) *by redesignating the second section 1011*
18 *(with respect to improving the training of State,*
19 *local, territorial, and tribal food safety officials), as*
20 *added by section 209(a) of the FDA Food Safety Mod-*
21 *ernization Act (Public Law 111–353), as section*
22 *1012.*

23 **SEC. 5. SCIENTIFIC MEETINGS.**

24 (a) *IN GENERAL.*—*Scientific meetings that are at-*
25 *tended by scientific or medical personnel, or other profes-*

1 sionals, of the Department of Health and Human Services
2 for whom attendance at such meeting is directly related to
3 their professional duties and the mission of the Depart-
4 ment—

5 (1) shall not be considered conferences for the
6 purposes of complying with Federal reporting require-
7 ments contained in annual appropriations Acts or in
8 this section; and

9 (2) shall not be considered conferences for pur-
10 poses of a restriction contained in an annual appro-
11 priations Act, based on Office of Management and
12 Budget Memorandum M-12-12 or any other regula-
13 tion restricting such travel.

14 (b) *LIMITATION.*—Nothing in this section shall be con-
15 strued to exempt travel for scientific meetings from Federal
16 regulations relating to travel.

17 (c) *REPORTS.*—Each operating division of the Depart-
18 ment of Health and Human Services shall prepare, and
19 post on an Internet website of the operating division, an
20 annual report on scientific meeting attendance and related
21 travel spending for each fiscal year. Such report shall in-
22 clude—

23 (1) general information concerning the scientific
24 meeting activities involved;

1 (2) *information concerning the total amount ex-*
2 *pended for such meetings;*

3 (3) *a description of all such meetings that were*
4 *attended by scientific or medical personnel, or other*
5 *professionals, of each such operating division where*
6 *the total amount expended by the operating division*
7 *associated with each such meeting are in excess of*
8 *\$30,000, including—*

9 (A) *the total amount of meeting expenses*
10 *incurred by the operating division for such meet-*
11 *ing;*

12 (B) *the location of such meeting;*

13 (C) *the date of such meeting;*

14 (D) *a brief explanation on how such meet-*
15 *ing advanced the mission of the operating divi-*
16 *sion; and*

17 (E) *the total number of individuals whose*
18 *travel expenses or other scientific meeting ex-*
19 *penses were paid by the operating division; and*

20 (4) *with respect to any such meeting where the*
21 *total expenses to the operating division exceeded*
22 *\$150,000, a description of the exceptional cir-*
23 *cumstances that necessitated the expenditure of such*
24 *amounts.*

1 **SEC. 6. REAGAN-UDALL FOUNDATION FOR THE FOOD AND**
2 **DRUG ADMINISTRATION.**

3 (a) *BOARD OF DIRECTORS.—*

4 (1) *COMPOSITION AND SIZE.—Section*
5 *770(d)(1)(C) of the Federal Food, Drug, and Cosmetic*
6 *Act (21 U.S.C. 379dd(d)(1)(C)) is amended—*

7 (A) *by redesignating clause (ii) as clause*
8 *(iii);*

9 (B) *by inserting after clause (i) the fol-*
10 *lowing:*

11 “(ii) *ADDITIONAL MEMBERS.—The*
12 *Board, through amendments to the bylaws*
13 *of the Foundation, may provide that the*
14 *number of voting members of the Board*
15 *shall be a number (to be specified in such*
16 *amendment) greater than 14. Any Board*
17 *positions that are established by any such*
18 *amendment shall be appointed (by majority*
19 *vote) by the individuals who, as of the date*
20 *of such amendment, are voting members of*
21 *the Board and persons so appointed may*
22 *represent any of the categories specified in*
23 *subclauses (I) through (V) of clause (i), so*
24 *long as no more than 30 percent of the total*
25 *voting members of the Board (including*
26 *members whose positions are established by*

1 *such amendment) are representatives of the*
2 *general pharmaceutical, device, food, cos-*
3 *metic, and biotechnology industries.”; and*
4 *(C) in clause (iii)(I), as redesignated by*
5 *subparagraph (A), by striking “The ex officio*
6 *members shall ensure” and inserting “The ex*
7 *officio members, acting pursuant to clause (i),*
8 *and the Board, acting pursuant to clause (ii),*
9 *shall ensure”.*

10 (2) *FEDERAL EMPLOYEES ALLOWED TO SERVE*
11 *ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of*
12 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
13 *379dd(d)(1)(C)), as redesignated by paragraph*
14 *(1)(A), is amended by adding at the end the fol-*
15 *lowing: “For purposes of this section, the term ‘em-*
16 *ployee of the Federal Government’ does not include a*
17 *‘special Government employee’, as that term is de-*
18 *fin ed in section 202(a) of title 18, United States*
19 *Code.”.*

20 (3) *STAGGERED TERMS.—Subparagraph (A) of*
21 *section 770(d)(3) of the Federal Food, Drug, and Cos-*
22 *metic Act (21 U.S.C. 379dd(d)(3)) is amended to read*
23 *as follows:*

24 *“(A) TERM.—The term of office of each*
25 *member of the Board appointed under para-*

1 *graph (1)(C)(i), and the term of office of any*
2 *member of the Board whose position is estab-*
3 *lished pursuant to paragraph (1)(C)(ii), shall be*
4 *4 years, except that—*

5 *“(i) the terms of offices for the members*
6 *of the Board initially appointed under*
7 *paragraph (1)(C)(i) shall expire on a stag-*
8 *gered basis as determined by the ex officio*
9 *members; and*

10 *“(ii) the terms of office for the persons*
11 *initially appointed to positions established*
12 *pursuant to paragraph (1)(C)(ii) may be*
13 *made to expire on a staggered basis, as de-*
14 *termined by the individuals who, as of the*
15 *date of the amendment establishing such po-*
16 *sitions, are members of the Board.”.*

17 **(b) EXECUTIVE DIRECTOR COMPENSATION.**—*Section*
18 *770(g)(2) of the Federal Food, Drug, and Cosmetic Act (21*
19 *U.S.C. 379dd(g)(2)) is amended by striking “but shall not*
20 *be greater than the compensation of the Commissioner”.*

21 **(c) SEPARATION OF FUNDS.**—*Section 770(m) of the*
22 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
23 *379dd(m)) is amended by striking “are held in separate*
24 *accounts from funds received from entities under subsection*
25 *(i)” and inserting “are managed as individual pro-*

1 *grammatic funds under subsection (i), according to best ac-*
 2 *counting practices”.*

3 **SEC. 7. NIH RESEARCH INFORMATION COLLECTION EX-**
 4 **EMPTED FROM PAPERWORK REDUCTION ACT.**

5 *Section 301 of the Public Health Service Act (42*
 6 *U.S.C. 241) is amended by adding to the end the following:*

7 *“(f) PAPERWORK REDUCTION.—Subchapter I of chap-*
 8 *ter 35 of title 44, United States Code, shall not apply to*
 9 *the collection of information during the conduct of research*
 10 *by the National Institutes of Health.”.*

11 **SEC. 8. STUDIES.**

12 *The Federal Food, Drug, and Cosmetic Act is amend-*
 13 *ed—*

14 *(1) in section 505(k)(5) (21 U.S.C. 355(k)(5))—*

15 *(A) in subparagraph (A), by inserting*
 16 *“and” after the semicolon;*

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

18 *(C) by redesignating subparagraph (C) as*
 19 *subparagraph (B);*

20 *(2) in section 505A (21 U.S.C. 355a), by striking*
 21 *subsection (p);*

22 *(3) in section 505B (21 U.S.C. 355c)—*

23 *(A) by striking subsection (l); and*

24 *(B) by redesignating subsection (m) as sub-*
 25 *section (l); and*

1 (4) in section 523 (21 U.S.C. 360m), by striking
2 subsection (d).

3 **SEC. 9. SUMMARY LEVEL REVIEW.**

4 Section 505(c) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355(c)) is amended by adding at the
6 end the following:

7 “(5)(A) The Secretary may rely upon qualified
8 data summaries to support the approval of a supple-
9 mental application, with respect to a qualified indi-
10 cation for a drug, submitted under subsection (b) or
11 section 351(a) of the Public Health Service Act, if
12 such supplemental application complies with sub-
13 paragraph (B).

14 “(B) A supplemental application is eligible for
15 review as described in subparagraph (A) only if—

16 “(i) there is existing data available and ac-
17 ceptable to the Secretary demonstrating the safe-
18 ty of the drug; and

19 “(ii) all data used to develop the qualified
20 data summaries are submitted to the Secretary
21 as part of the supplemental application.

22 “(C) In this paragraph—

23 “(i) the term ‘qualified indication’ means
24 an indication for a drug that the Secretary de-

1 *termines to be appropriate for summary level re-*
2 *view under this paragraph; and*

3 *“(i) the term ‘qualified data summary’*
4 *means a summary of clinical data that dem-*
5 *onstrates the safety and effectiveness of a drug*
6 *with respect to a qualified indication.”.*

7 **SEC. 10. DRUG SURVEILLANCE.**

8 *(a) NEW DRUGS.—Section 505(k)(5) of the Federal*
9 *Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)(5)), as*
10 *amended by section 8, is further amended—*

11 *(1) in subparagraph (A), by striking “, bi-weekly*
12 *screening” and inserting “screenings”;*

13 *(2) in subparagraph (B), as redesignated by sec-*
14 *tion 8(1)(C), by striking the period at the end and in-*
15 *serting “; and”; and*

16 *(3) by adding at the end the following:*

17 *“(C) make available on the Internet website*
18 *of the Food and Drug Administration—*

19 *“(i) guidelines, developed with input*
20 *from experts qualified by scientific training*
21 *and experience to evaluate the safety and ef-*
22 *fectiveness of drugs, that detail best prac-*
23 *tices for drug safety surveillance using the*
24 *FDA Adverse Event Reporting Systems;*
25 *and*

1 “(i) criteria for public posting of ad-
2 verse event signals.”.

3 (b) *FAERS REVISION*.—Section 505(r)(2)(D) of the
4 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.
5 355(r)(2)(D)) is amended by striking “, by 18 months” and
6 all that follows through the semicolon at the end of the sub-
7 paragraph and inserting “and making publicly available
8 on the Internet Web site established under paragraph (1)
9 best practices for drug safety surveillance activities for
10 drugs newly approved under this section or section 351 of
11 the *Public Health Service Act*”.

12 (c) *RISK EVALUATION AND MITIGATION STRATE-*
13 *GIES*.—Section 505–1(f)(5) of the *Federal Food, Drug, and*
14 *Cosmetic Act* (21 U.S.C. 355–1(f)(5)) is amended—

15 (1) in the matter preceding subparagraph (A),
16 by inserting “or other advisory committee” after “(or
17 successor committee)”; and

18 (2) in subparagraph (B), by striking “at least
19 annually,” and inserting “periodically”.

20 **SEC. 11. BIOLOGICAL PRODUCT INNOVATION.**

21 Section 351(j) of the *Public Health Service Act* (42
22 U.S.C. 262(j)) is amended by striking “except that” and
23 all that follows through the period at the end and inserting
24 “except that—

1 “(1) a product for which a license has been ap-
 2 proved under this section shall not be required to have
 3 an approved application under section 505 of such
 4 Act; and

5 “(2) those provisions of the Federal Food, Drug,
 6 and Cosmetic Act that refer to an official compen-
 7 dium as defined under section 201(j) of such Act shall
 8 not apply to a biological product subject to regulation
 9 under this section.”.

10 **SEC. 12. EXPANDED ACCESS POLICY.**

11 Chapter V of the Federal Food, Drug, and Cosmetic
 12 Act is amended by inserting after section 561 (21 U.S.C.
 13 360bbb) the following:

14 **“SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR IN-**
 15 **VESTIGATIONAL DRUGS.**

16 “(a) *IN GENERAL.*—The manufacturer or distributor
 17 of one or more investigational drugs for the diagnosis, cure,
 18 mitigation, treatment, or prevention of one or more serious
 19 diseases or conditions shall make available the policy of the
 20 manufacturer or distributor on evaluating and responding
 21 to requests submitted under section 561(b) for provision of
 22 such a drug.

23 “(b) *PUBLIC AVAILABILITY OF EXPANDED ACCESS*
 24 *POLICY.*—The policies under subsection (a) shall be made
 25 public and readily available, such as by posting such poli-

1 *cies on a publicly available Internet website. Such policies*
2 *may be generally applicable to all investigational drugs of*
3 *such manufacturer or distributor.*

4 “(c) *CONTENT OF POLICY.*—*A policy described in sub-*
5 *section (a) shall include—*

6 “(1) *contact information for the manufacturer or*
7 *distributor to facilitate communication about requests*
8 *described in subsection (a);*

9 “(2) *procedures for making such requests;*

10 “(3) *the general criteria the manufacturer or dis-*
11 *tributor will use to evaluate such requests for indi-*
12 *vidual patients, and for responses to such requests;*
13 *and*

14 “(4) *the length of time the manufacturer or dis-*
15 *tributor anticipates will be necessary to acknowledge*
16 *receipt of such requests.*

17 “(d) *NO GUARANTEE OF ACCESS.*—*The posting of*
18 *policies by manufacturers and distributors under subsection*
19 *(a) shall not serve as a guarantee of access to any specific*
20 *investigational drug by any individual patient.*

21 “(e) *REVISED POLICY.*—*Nothing in this section shall*
22 *prevent a manufacturer or distributor from revising a pol-*
23 *icy required under this section at any time.*

1 “(f) *APPLICATION.*—*This section shall apply to a man-*
 2 *ufacturer or distributor with respect to an investigational*
 3 *drug beginning on the later of—*

4 “(1) *the date that is 60 calendar days after the*
 5 *date of enactment of the FDA and NIH Workforce*
 6 *Authorities Modernization Act; or*

7 “(2) *the first initiation of a phase 2 or phase 3*
 8 *study (as such terms are defined in section 312.21(b)*
 9 *and (c) of title 21, Code of Federal Regulations (or*
 10 *any successor regulations)) with respect to such inves-*
 11 *tigational drug.”.*

12 **SEC. 13. FINALIZING DRAFT GUIDANCE ON EXPANDED AC-**
 13 **CESS.**

14 (a) *IN GENERAL.*—*Not later than 1 year after the date*
 15 *of enactment of this Act, the Secretary of Health and*
 16 *Human Services shall finalize the draft guidance entitled*
 17 *“Expanded Access to Investigational Drugs for Treatment*
 18 *Use—Qs & As”, dated May 2013.*

19 (b) *CONTENTS.*—*The final guidance described in sub-*
 20 *section (a) shall explain how the Secretary of Health and*
 21 *Human Services considers and uses adverse drug event data*
 22 *reported by investigators in the case of data reported from*
 23 *use under a request submitted under section 561(b) of the*
 24 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 25 *360bbb(b)).*

1 **SEC. 14. AMENDMENTS TO THE ORPHAN DRUG ACT.**

2 *Section 5 of the Orphan Drug Act (21 U.S.C. 360ee)*
3 *is amended—*

4 *(1) in subsection (a), by striking paragraph (1)*
5 *and inserting the following: “(1) defraying the costs*
6 *of developing drugs for rare diseases or conditions, in-*
7 *cluding qualified testing expenses,”; and*

8 *(2) in subsection (b)(1)—*

9 *(A) in subparagraph (A)(ii), by striking*
10 *“and” after the semicolon;*

11 *(B) in subparagraph (B), by striking the*
12 *period and inserting “; and”; and*

13 *(C) by adding at the end the following:*

14 *“(C) prospectively planned and designed ob-*
15 *servational studies and other analyses conducted*
16 *to assist in the understanding of the natural his-*
17 *tory of a rare disease or condition and in the de-*
18 *velopment of a therapy, including studies and*
19 *analyses to—*

20 *“(i) develop or validate a drug develop-*
21 *ment tool related to a rare disease or condi-*
22 *tion; or*

23 *“(ii) understand the full spectrum of*
24 *the disease manifestations, including de-*
25 *scribing genotypic and phenotypic varia-*
26 *bility and identifying and defining distinct*

1 *subpopulations affected by a rare disease or*
2 *condition.”.*

3 **SEC. 15. STANDARDS FOR REGENERATIVE MEDICINE AND**
4 **ADVANCED THERAPIES.**

5 *Subchapter A of chapter V of the Federal Food, Drug,*
6 *and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by*
7 *inserting after section 506F the following:*

8 **“SEC. 506G. STANDARDS FOR REGENERATIVE MEDICINE**
9 **AND ADVANCED THERAPIES.**

10 *“(a) IN GENERAL.—The Secretary, in consultation*
11 *with the National Institute of Standards and Technology*
12 *and stakeholders (including regenerative medicine and ad-*
13 *vanced therapies manufacturers and clinical trial sponsors,*
14 *contract manufacturers, academic institutions, practicing*
15 *clinicians, regenerative medicine and advanced therapies*
16 *industry organizations, and standard setting organiza-*
17 *tions), shall facilitate an effort to coordinate and prioritize*
18 *the development of standards, through a transparent public*
19 *process, that will help support product development, evalua-*
20 *tion, and review, with respect to regenerative medicine and*
21 *advanced therapies, through regulatory predictability, in-*
22 *cluding with regard to manufacturing processes and con-*
23 *trols for regenerative medicine and advanced therapies*
24 *products.*

25 *“(b) ACTIVITIES.—*

1 “(1) *IN GENERAL.*—*In carrying out this section,*
2 *the Secretary shall continue to—*

3 “(A) *identify opportunities to help advance*
4 *the development of regenerative medicine and ad-*
5 *vanced therapies;*

6 “(B) *identify opportunities for the develop-*
7 *ment of laboratory regulatory science research*
8 *and documentary standards that the Secretary*
9 *determines would help support the development,*
10 *evaluation, and review of regenerative medicine*
11 *and advanced therapies through regulatory pre-*
12 *dictability; and*

13 “(C) *work with stakeholders, such as those*
14 *described in subsection (a), as appropriate, in*
15 *the development of such standards.*

16 “(2) *REGULATIONS AND GUIDANCE.*—*After the*
17 *development of standards as described in subsection*
18 *(a), the Secretary shall review relevant regulations*
19 *and guidance and, through a transparent public proc-*
20 *ess, update such regulations and guidance as the Sec-*
21 *retary determines appropriate.*

22 “(c) *DEFINITION.*—*For purposes of this section, the*
23 *term ‘regenerative medicine and advanced therapies’ in-*
24 *cludes cell therapy, gene therapy, gene-modified cell ther-*
25 *apy, therapeutic tissue engineering products, human cell*

1 *and tissue products, and combination products using any*
2 *such therapies or products.”.*

3 **SEC. 16. GOOD GUIDANCE PRACTICES.**

4 *(a) IN GENERAL.—Section 701(h)(1)(C) of the Federal*
5 *Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) is*
6 *amended—*

7 *(1) by moving the margin of clause (ii) 2 ems*
8 *to the left; and*

9 *(2) by adding at the end the following:*

10 *“(iii) When proposing or finalizing*
11 *any guidance document under this subpara-*
12 *graph, the Secretary shall include in the*
13 *guidance document a statement, the con-*
14 *tents of which are committed to the discre-*
15 *tion of the Secretary—*

16 *“(I) explaining why the interpre-*
17 *tation or policy set forth in such guid-*
18 *ance document is being provided in a*
19 *nonbinding guidance document and*
20 *not established through rulemaking;*
21 *and*

22 *“(II) identifying each specific*
23 *statutory provision or regulation being*
24 *interpreted in the guidance document*

1 or authorizing a policy decision de-
2 scribed in the guidance document.”.

3 (b) *EFFECTIVE DATE.*—The amendment made under
4 subsection (a)(2) shall take effect with respect to any appli-
5 cable guidance documents that are issued on or after the
6 date that is 3 months after the date of enactment of this
7 Act.

8 **SEC. 17. PAPERWORK REDUCTION ACT WAIVER DURING A**
9 **PUBLIC HEALTH EMERGENCY.**

10 Section 319 of the Public Health Service Act (42
11 U.S.C. 247d) is amended by adding at the end the fol-
12 lowing:

13 “(f) *DETERMINATION WITH RESPECT TO PAPERWORK*
14 *REDUCTION ACT WAIVER DURING A PUBLIC HEALTH*
15 *EMERGENCY.*—

16 “(1) *DETERMINATION.*—If the Secretary deter-
17 mines, after consultation with such public health offi-
18 cials as may be necessary, that—

19 “(A)(i) the criteria set forth for a public
20 health emergency under paragraph (1) or (2) of
21 subsection (a) has been met; or

22 “(ii) a disease or disorder, including a
23 novel and emerging public health threat, is sig-
24 nificantly likely to become a public health emer-
25 gency; and

1 “(B) *the circumstances of such public health*
2 *emergency, or potential for such significantly*
3 *likely public health emergency, including the spe-*
4 *cific preparation for and response to such public*
5 *health emergency or threat, necessitate a waiver*
6 *from the requirements of subchapter I of chapter*
7 *35 of title 44, United States Code (commonly re-*
8 *ferred to as the Paperwork Reduction Act);*
9 *then the requirements of such subchapter I with re-*
10 *spect to voluntary collection of information shall not*
11 *be applicable during the immediate investigation of,*
12 *and response to, such public health emergency during*
13 *the period of such public health emergency or the pe-*
14 *riod of time necessary to determine if a disease or dis-*
15 *order, including a novel and emerging public health*
16 *threat, will become a public health emergency as pro-*
17 *vided for in this paragraph. The requirements of such*
18 *subchapter I with respect to voluntary collection of*
19 *information shall not be applicable during the imme-*
20 *diately post-response review regarding such public*
21 *health emergency if such immediate post-response re-*
22 *view does not exceed a reasonable length of time.*

23 “(2) *TRANSPARENCY.—If the Secretary deter-*
24 *mines that a waiver is necessary under paragraph*
25 *(1), the Secretary shall promptly post on the Internet*

1 *website of the Department of Health and Human*
2 *Services a brief justification for such waiver, the an-*
3 *ticipated period of time such waiver will be in effect,*
4 *and the agencies and offices within the Department of*
5 *Health and Human Services to which such waiver*
6 *shall apply, and update such information posted on*
7 *the Internet website of the Department of Health and*
8 *Human Services, as applicable.*

9 “(3) *EFFECTIVENESS OF WAIVER.*—*Any waiver*
10 *under this subsection shall take effect on the date on*
11 *which the Secretary posts information on the Internet*
12 *website as provided for in this subsection.*

13 “(4) *TERMINATION OF WAIVER.*—*Upon deter-*
14 *mining that the circumstances necessitating a waiver*
15 *under paragraph (1) no longer exist, the Secretary*
16 *shall promptly update the Internet website of the De-*
17 *partment of Health and Human Services to reflect the*
18 *termination of such waiver.*

19 “(5) *LIMITATIONS.*—

20 “(A) *PERIOD OF WAIVER.*—*The period of a*
21 *waiver under paragraph (1) shall not exceed the*
22 *period of time for the related public health emer-*
23 *gency, including a public health emergency de-*
24 *clared pursuant to subsection (a), and any im-*
25 *mediate post-response review regarding the pub-*

1 *lic health emergency consistent with the require-*
2 *ments of this subsection.*

3 “(B) *SUBSEQUENT COMPLIANCE.*—*An ini-*
4 *tiative subject to a waiver under paragraph (1)*
5 *that is ongoing after the date on which the wai-*
6 *ver expires, shall be subject to the requirements of*
7 *subchapter I of chapter 35 of title 44, United*
8 *States Code, and the Secretary shall ensure that*
9 *compliance with such requirements occurs in as*
10 *timely a manner as possible based on the appli-*
11 *cable circumstances, but not to exceed 30 cal-*
12 *endar days after the expiration of the applicable*
13 *waiver.”.*

14 **SEC. 18. TECHNICAL CORRECTIONS.**

15 (a) *REFERENCES.*—*Except as otherwise expressly pro-*
16 *vided, whenever in this subsection an amendment is ex-*
17 *pressed in terms of an amendment to a section or other pro-*
18 *vision, the reference shall be considered to be made to that*
19 *section or other provision of the Federal Food, Drug, and*
20 *Cosmetic Act (21 U.S.C. 301 et seq.).*

21 (b) *AMENDMENTS.*—

22 (1) *PROHIBITED ACTS.*—*Section 301(r) of the*
23 *Act (21 U.S.C. 331(r)) is amended by inserting “,*
24 *drug,” after “device” each place the term appears.*

1 (2) *NEW DRUGS*.—Section 505 of the Act (21
2 U.S.C. 355) is amended—

3 (A) in subsection (d), in the last sentence,
4 by striking “premarket approval” and inserting
5 “marketing approval”; and

6 (B) in subsection (q)(5)(A), by striking
7 “subsection (b)(2) or (j) of the Act or 351(k)”
8 and inserting “subsection (b)(2) or (j) of this sec-
9 tion or section 351(k)”.

10 (3) *RISK EVALUATION AND MITIGATION STRATE-*
11 *GIES*.—Section 505–1(h) of the Act (21 U.S.C. 355–
12 1(h)) is amended—

13 (A) in paragraph (2)(A)(iii)—

14 (i) in the clause heading, by striking
15 “LABEL” and inserting “LABELING”;

16 (ii) by striking “label” each place the
17 term appears and inserting “labeling”; and

18 (iii) by striking “sponsor” and insert-
19 ing “responsible person”; and

20 (B) in paragraph (8), by striking “and
21 (7).” and inserting “and (7)”.

22 (4) *PEDIATRIC STUDY PLANS*.—Section 505B of
23 the Act (21 U.S.C. 355c) is amended—

24 (A) in subsection (e)—

25 (i) in paragraph (2)—

1 (I) in subparagraph (A), in the
2 matter preceding clause (i), by insert-
3 ing “study” after “initial pediatric”
4 each place the term appears; and

5 (II) in subparagraph (B), in the
6 subparagraph heading, by striking
7 “INITIAL PLAN” and inserting “INITIAL
8 PEDIATRIC STUDY PLAN”;

9 (ii) in paragraph (5), by inserting
10 “AGREED INITIAL PEDIATRIC STUDY” before
11 “PLAN” in the paragraph heading; and

12 (iii) in paragraph (6), by striking
13 “agreed initial pediatric plan” and insert-
14 ing “agreed initial pediatric study plan”;
15 and

16 (B) in subsection (f)(1), by inserting “and
17 any significant amendments to such plans,”
18 after “agreed initial pediatric study plans,”.

19 (5) *DISCONTINUANCE OR INTERRUPTION IN THE*
20 *PRODUCTION OF LIVE-SAVING DRUGS.*—Section 506C
21 of the Act (21 U.S.C. 356c) is amended—

22 (A) in subsection (c), by striking “dis-
23 continuation” and inserting “discontinuance”;
24 and

1 (B) in subsection (g)(1), by striking “sec-
2 tion 505(j) that could help” and inserting “sec-
3 tion 505(j), that could help”.

4 (6) ANNUAL REPORTING ON DRUG SHORTAGES.—
5 Section 506C–1(a) of the Act (21 U.S.C. 331(a)) is
6 amended, in the matter before paragraph (1)—

7 (A) by striking “Not later than the end of
8 calendar year 2013, and not later than the end
9 of each calendar year thereafter,” and inserting
10 “Not later than March 31 of each calendar
11 year,”; and

12 (B) by inserting “, with respect to the pre-
13 ceding calendar year,” after “a report”.

14 (7) DRUG SHORTAGE LIST.—Section
15 506E(b)(3)(E) of the Act (21 U.S.C. 356e(b)(3)(E)) is
16 amended by striking “discontinuation” and inserting
17 “discontinuance”.

18 (8) INSPECTIONS OF ESTABLISHMENTS.—Section
19 510(h) of the Act (21 U.S.C. 360(h)) is amended—

20 (A) in paragraph (4), in the matter pre-
21 ceding subparagraph (A), by striking “estab-
22 lishing the risk-based scheduled” and inserting
23 “establishing a risk-based schedule”; and

24 (B) in paragraph (6)—

1 (i) in subparagraph (A), by striking
2 “fiscal” and inserting “calendar” each place
3 the term appears; and

4 (ii) in subparagraph (B), by striking
5 “an active ingredient of a drug, a finished
6 drug product, or an excipient of a drug”
7 and inserting “an active ingredient of a
8 drug or a finished drug product”.

9 (9) *CLASSIFICATION OF DEVICES INTENDED FOR*
10 *HUMAN USE.*—Section 513(f)(2)(A) of the Act (21
11 U.S.C. 360c(f)(2)(A)) is amended—

12 (A) in clause (i), by striking “within 30
13 days”; and

14 (B) in clause (iv), by striking “low-mod-
15 erate” and inserting “low to moderate”.

16 (10) *PREMARKET APPROVAL.*—Section 515(a)(1)
17 of the Act (21 U.S.C. 360e(a)(1)) is amended by strik-
18 ing “subject to a an order” and inserting “subject to
19 an order”.

20 (11) *PROGRAM TO IMPROVE THE DEVICE RECALL*
21 *SYSTEM.*—Section 518A of the Act (21 U.S.C. 360h-
22 1) is amended—

23 (A) by striking subsection (c); and

24 (B) by redesignating subsection (d) as sub-
25 section (c).

1 (12) *UNIQUE DEVICE IDENTIFIER.*—Section
2 519(f) of the Act (21 U.S.C. 360i(f)) is amended by
3 striking “and life sustaining” and inserting “or life
4 sustaining”.

5 (13) *PRIORITY REVIEW FOR QUALIFIED INFEC-*
6 *TIOUS DISEASE PRODUCTS.*—Section 524A of the Act
7 (21 U.S.C. 360n–1) is amended—

8 (A) by striking “If the Secretary” and in-
9 serting the following:

10 “(a) *IN GENERAL.*—If the Secretary”;

11 (B) by striking “any” and inserting “the
12 first”; and

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

14 “(b) *CONSTRUCTION.*—Nothing in this section shall
15 prohibit the Secretary from giving priority review to a
16 human drug application or efficacy supplement submitted
17 for approval under section 505(b) that otherwise meets the
18 criteria for the Secretary to grant priority review.”.

19 (14) *CONSULTATION WITH EXTERNAL EXPERTS*
20 *ON RARE DISEASES, TARGETED THERAPIES, AND GE-*
21 *NETIC TARGETING OF TREATMENTS.*—Section
22 569(a)(2)(A) of the Act (21 U.S.C. 360bbb–
23 8(a)(2)(A)) is amended, in the first sentence, by strik-
24 ing “subsection (c)” and inserting “subsection (b)”.

1 (15) *OPTIMIZING GLOBAL CLINICAL TRIALS.*—
2 *Section 569A(c) of the Act (21 U.S.C. 360bbb–8a(c))*
3 *is amended by inserting “or under the Public Health*
4 *Service Act” after “this Act”.*

5 (16) *USE OF CLINICAL INVESTIGATION DATA*
6 *FROM OUTSIDE THE UNITED STATES.*—*Section 569B*
7 *of the Act (21 U.S.C. 360bbb–8b) is amended by strik-*
8 *ing “drug or device” and inserting “drug, biological*
9 *product, or device” each place the term appears.*

10 (17) *MEDICAL GASES DEFINITIONS.*—*Section*
11 *575(1)(H) of the Act (21 U.S.C. 360ddd(1)(H)) is*
12 *amended—*

13 (A) *by inserting “for a new drug” after*
14 *“any period of exclusivity”; and*

15 (B) *by inserting “or any period of exclu-*
16 *sivity for a new animal drug under section*
17 *512(c)(2)(F),” after “section 505A,”.*

18 (18) *REGULATION OF MEDICAL GASES.*—*Section*
19 *576(a) of the Act (21 U.S.C. 360ddd–1(a)) is amend-*
20 *ed—*

21 (A) *in the matter preceding subparagraph*
22 (A) *of paragraph (1), by inserting “who seeks to*
23 *initially introduce or deliver for introduction a*
24 *designated medical gas into interstate commerce”*
25 *after “any person”; and*

1 (B) in paragraph (3)—

2 (i) in subparagraph (A)—

3 (I) in clause (i)(VIII), by insert-
4 ing “for a new drug” after “any period
5 of exclusivity”; and

6 (II) in clause (ii), in the matter
7 preceding subclause (I), by inserting
8 “the” before “final use”; and

9 (ii) in subparagraph (B)—

10 (I) in clause (i), by inserting “for
11 a new drug” after “any period of ex-
12 clusivity”; and

13 (II) in clause (ii), by inserting a
14 comma after “drug product”.

15 (19) *INAPPLICABILITY OF DRUG FEES TO DES-*
16 *IGNATED MEDICAL GASES.*—Section 577 of this Act
17 (21 U.S.C. 360ddd–2) is amended by inserting “or
18 740(a)” after “section 736(a)”.

19 (20) *CONFLICTS OF INTEREST.*—Section
20 712(e)(1)(B) of the Act (21 U.S.C. 379d–1(e)(1)(B))
21 is amended by striking “services” and inserting
22 “service”.

23 (21) *AUTHORITY TO ASSESS AND USE BIO-*
24 *SIMILAR BIOLOGICAL PRODUCT FEES.*—Section

1 744H(a) of the Act (21 U.S.C. 379j–52(a)) is amend-
2 ed—

3 (A) in paragraph (1)(A)(v), by striking
4 “Biosimilars User Fee Act of 2012” and insert-
5 ing “Biosimilar User Fee Act of 2012”; and

6 (B) in paragraph (2)(B), by striking
7 “Biosimilars User Fee Act of 2012” and insert-
8 ing “Biosimilar User Fee Act of 2012”.

9 (22) *REGISTRATION OF COMMERCIAL IMPORT-*
10 *ERS.*—

11 (A) *AMENDMENT.*—Section 801(s)(2) of the
12 Act (21 U.S.C. 381(s)(2)) is amended by adding
13 at the end the following:

14 “(D) *EFFECTIVE DATE.*—In establishing the
15 effective date of the regulations under subpara-
16 graph (A), the Secretary shall, in consultation
17 with the Secretary of Homeland Security acting
18 through U.S. Customs and Border Protection, as
19 determined appropriate by the Secretary of
20 Health and Human Services, provide a reason-
21 able period of time for an importer of a drug to
22 comply with good importer practices, taking into
23 account differences among importers and types
24 of imports, including based on the level of risk
25 posed by the imported product.”.

1 (B) *CONFORMING AMENDMENT.*—Section
2 714 of the *Food and Drug Administration Safety*
3 *and Innovation Act (Public Law 112–144; 126*
4 *Stat. 1074)* is amended by striking subsection
5 (d).

6 (23) *RECOGNITION OF FOREIGN GOVERNMENT IN-*
7 *SPECTIONS.*—Section 809(a)(2) of the Act (21 U.S.C.
8 384e(a)(2)) is amended by striking “conduction” and
9 inserting “conducting”.

10 (24) *FINDINGS RELATING TO DRUG APPROVAL.*—
11 Section 901(a)(1)(A) of the *Food and Drug Adminis-*
12 *tration Safety and Innovation Act (Public Law 112–*
13 *144; 21 U.S.C. 356 note)* is amended by striking “se-
14 *rious and life-threatening diseases”* and inserting “se-
15 *rious or life-threatening diseases”*.

16 (25) *REPORTING OF INCLUSION OF DEMO-*
17 *GRAPHIC SUBGROUPS.*—Section 907 of the *Food and*
18 *Drug Administration Safety and Innovation Act*
19 *(Public Law 112–144; 126 Stat. 1092, 1093)* is
20 amended—

21 (A) in the section heading, by striking
22 “**BIOLOGICS**” in the heading and inserting
23 “**BIOLOGICAL PRODUCTS**”; and

1 (B) in subsection (a)(2)(B), by striking
2 “applications for new drug applications” and
3 inserting “new drug applications”.

4 (26) *COMBATING PRESCRIPTION DRUG ABUSE.*—
5 Section 1122 of the Food and Drug Administration
6 Safety and Innovation Act (Public Law 112–144; 126
7 Stat. 1112, 1113) is amended—

8 (A) in subsection (a)(2), by striking
9 “dependance” and inserting “dependence”; and

10 (B) in subsection (c), by striking “promul-
11 gate” and inserting “issue”.

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114TH CONGRESS
2^D SESSION
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A BILL

To update the authorizing provisions relating to the workforces of the National Institutes of Health and the Food and Drug Administration, and for other purposes.

APRIL 18, 2016

Reported with an amendment