II

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.

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

~~**SECTION 1. SHORT TITLE.**~~

~~This Act may be cited as the "FDA and NIH Workforce Authorities Modernization Act".~~

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

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

(1) in the section heading, by inserting "AND BIOMEDICAL PRODUCT ASSESSMENT" after "RESEARCH";

(2) in subsection (a)—

(A) in paragraph (1), by striking "Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members" and inserting "Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the 'Service'), not to exceed 2,000 members, the purpose of which is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment";

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

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

system in order to offset the number of members serving in the Service.''; and

(C) by adding at the end the following:

''(3) The Secretary shall assign experts under this section to agencies within the Department of Health and Human Services taking into account the need for the expertise of such expert.'';

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''or clinical research evaluation'' and inserting '', clinical research evaluation, or biomedical product assessment''; and

(B) in paragraph (1), by inserting ''or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field,'' after the comma;

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

(5) by striking subsection (e); and

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

(b) GAO STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the effectiveness of the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a) and the impact of such amendments, if any, on all agencies or departments of the Department of Health and Human Services, and, not later than 4 years after the date of enactment of this Act, shall submit a report based on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) CONTENT OF STUDY AND REPORT.—The study and report under paragraph (1) shall include an examination of the extent to which recruitment and retention of outstanding and qualified scientific, medical, or technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment has improved or otherwise has been affected by the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a), including by

~~determining, during the period between the date of enactment of this Act and the completion of the study—~~

~~(A) the total number of members recruited and retained under the Senior Biomedical Research and Biomedical Product Assessment Service under such section 228, and the effect of increasing the number of members eligible for such Service;~~

~~(B) the number of members of such Senior Biomedical Research and Biomedical Product Assessment Service hired with a doctoral level degree in biomedicine or a related field, or doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field; and~~

~~(C) how many Senior Biomedical Research and Biomedical Product Assessment Service members have been hired by each agency or department of the Department of Health and Human Services, and how such Department assigns such members to each agency or department.~~

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

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

"SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

"(a) IN GENERAL.—The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Such positions shall be within the competitive service.

"(b) COMPENSATION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Commissioner of Food and Drugs may determine and fix—

"(A) the annual rate of pay of any individual appointed under subsection (a); and

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

fied scientific, technical, or professional personnel appointed to a position described in subsection (a) before the date of enactment of this section.

''(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code.

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

''(c) RULE OF CONSTRUCTION.—The authorities under this section shall not be construed to affect the authority provided under section 714.

''(d) REPORT ON WORKFORCE PLANNING.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the FDA and NIH Workforce Authorities Modernization Act, the Secretary shall submit a report on workforce planning to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines the extent to which the Food and Drug Administration has a critical need for qualified

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

"(A) an analysis of the workforce needs at the Food and Drug Administration and the Secretary's strategic plan for addressing such needs, including through use of the authority under this section; and

"(B) a recruitment and retention plan for hiring qualified scientific, technical, and professional candidates, which may include the use of—

"(i) recruitment through non-governmental recruitment or placement agencies;

"(ii) recruitment through academic institutions;

"(iii) recruitment or hiring bonuses, if applicable;

"(iv) recruitment using targeted direct hiring authorities; and

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

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

the Commissioner of Food and Drugs that would help the Food and Drug Administration to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.''.

(b) GAO STUDY AND REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the ability of the Food and Drug Administration to hire, train, and retain qualified scientific, technical, and professional staff, not including contractors, necessary to fulfill the mission of the Food and Drug Administration to protect and promote public health. Not later than January 1, 2022, the Comptroller General shall submit a report on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

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

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

biomedical research, clinical research evaluation, and biomedical product assessment;

(B) the extent to which critical staffing needs exist at the Food and Drug Administration, and barriers to hiring, training, and retaining qualified staff, if any;

(C) an examination of the recruitment and retention strategies of the Food and Drug Administration, including examining any strategic workforce plan, focused on improving scientific, technical, and professional staff recruitment and retention; and

(D) recommendations for potential improvements that would address staffing needs of the Food and Drug Administration.

SEC. 4. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

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

"SEC. 1014. FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

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

tute') for a major disease area or areas. With respect to the major disease area of focus of an Institute, such Institute shall develop and implement processes for coordination of activities, as applicable to such major disease area or areas, between the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health (for the purposes of this section, referred to as the 'Centers'). Such activities may include—

''(1) coordination of staff from the Centers with diverse product expertise in the diagnosis, cure, mitigation, treatment, or prevention of the specific diseases relevant to the major disease area of focus of the Institute;

''(2) streamlining, where appropriate, the review of medical products to diagnose, cure, mitigate, treat, or prevent the major disease area of focus of the Institute, applying relevant standards under sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and other applicable authorities;

''(3) promotion of scientific programs within the Centers related to the major disease area of focus of the Institute;

''(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;

''(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and

''(6) facilitation of the collaborative relationships of the Centers with other agencies within the Department of Health and Human Services regarding the major disease area of focus of the Institute.

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

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

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

''(d) TERMINATION OF INSTITUTES.—The Secretary may terminate any Institute established pursuant to this section if the Secretary determines such Institute is no longer benefitting the public health. Not less than 60 days prior to so terminating an Institute, the Secretary shall provide public notice, including the rationale for such termination.''.

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

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

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

SEC. 5. SCIENTIFIC MEETINGS.

(a) IN GENERAL.—Scientific meetings that are attended by scientific or medical personnel, or other professionals, of the Department of Health and Human Services for whom attendance at such meeting is directly related

to their professional duties and the mission of the Department—

(1) shall not be considered conferences for the purposes of complying with Federal reporting requirements contained in annual appropriations Acts or in this section; and

(2) shall not be considered conferences for purposes of a restriction contained in an annual appropriations Act, based on Office of Management and Budget Memorandum M–12–12 or any other regulation restricting such travel.

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

(c) REPORTS.—Each operating division of the Department of Health and Human Services shall prepare, and post on an Internet website of the operating division, an annual report on scientific meeting attendance and related travel spending for each fiscal year. Such report shall include—

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

(2) information concerning the total amount expended for such meetings;

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

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

~~(B) the location of such meeting;~~

~~(C) the date of such meeting;~~

~~(D) a brief explanation on how such meeting advanced the mission of the operating division; and~~

~~(E) the total number of individuals whose travel expenses or other scientific meeting expenses were paid by the operating division; and~~

~~(4) with respect to any such meeting where the total expenses to the operating division exceeded $150,000, a description of the exceptional circumstances that necessitated the expenditure of such amounts.~~

~~SEC. 6. REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.~~

~~(a) BOARD OF DIRECTORS.—~~

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

(A) by redesignating clause (ii) as clause (iii);

(B) by inserting after clause (i) the following:

"(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by such amendment) are representatives of the general pharmaceutical, device,

food, cosmetic, and biotechnology industries.''; and

(C) in clause (iii)(I), as redesignated by subparagraph (A), by striking ''The ex officio members shall ensure'' and inserting ''The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure''.

(2) FEDERAL EMPLOYEES ALLOWED TO SERVE ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)), as redesignated by paragraph (1)(A), is amended by adding at the end the following: ''For purposes of this section, the term 'employee of the Federal Government' does not include a 'special Government employee', as that term is defined in section 202(a) of title 18, United States Code.''.

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

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any

member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

"(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members; and

"(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.".

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

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

section (i)'' and inserting ''are managed as individual programmatic funds under subsection (i), according to best accounting practices''.

SEC. 7. NIH RESEARCH INFORMATION COLLECTION EXEMPTED FROM PAPERWORK REDUCTION ACT.

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

''(f) PAPERWORK REDUCTION.—Subchapter I of chapter 35 of title 44, United States Code, shall not apply to the collection of information during the conduct of research by the National Institutes of Health.''.

SEC. 8. STUDIES.

The Federal Food, Drug, and Cosmetic Act is amended—

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

(A) in subparagraph (A), by inserting ''and'' after the semicolon;

(B) by striking subparagraph (B); and

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

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

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

~~(A) by striking subsection (l); and~~

~~(B) by redesignating subsection (m) as subsection (l); and~~

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "FDA and NIH Workforce Authorities Modernization Act".

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

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

(1) in the section heading, by inserting "AND BIOMEDICAL PRODUCT ASSESSMENT" after "RESEARCH";

(2) in subsection (a)—

(A) in paragraph (1), by striking "Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members" and inserting "Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the 'Service'), not to exceed 2,000 members, the purpose of which is to recruit

and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment";

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

"(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service."; and

(C) by adding at the end the following:

"(3) The Secretary shall assign experts under this section to agencies within the Department of Health and Human Services taking into account the need for the expertise of such expert.";

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "or clinical research evaluation" and inserting ", clinical research evaluation, or biomedical product assessment"; and

(B) in paragraph (1), by inserting "or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field," after the comma;

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

(5) by striking subsection (e); and

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

(b) GAO STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the effectiveness of the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a) and the impact of such amendments, if any, on all agencies or departments of the Department of Health and Human Services, and, not later than 4 years after the date of enactment of this Act, shall submit a report based on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

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

an examination of the extent to which recruitment and retention of outstanding and qualified scientific, medical, or technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment has improved or otherwise has been affected by the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a), including by determining, during the period between the date of enactment of this Act and the completion of the study—

(A) the total number of members recruited and retained under the Senior Biomedical Research and Biomedical Product Assessment Service under such section 228, and the effect of increasing the number of members eligible for such Service;

(B) the number of members of such Senior Biomedical Research and Biomedical Product Assessment Service hired with a doctoral level degree in biomedicine or a related field, or doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field; and

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

members have been hired by each agency or department of the Department of Health and Human Services, and how such Department assigns such members to each agency or department.

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

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

"SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

"(a) IN GENERAL.—The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Such positions shall be within the competitive service.

"(b) COMPENSATION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the

Commissioner of Food and Drugs may determine and fix—

"(A) the annual rate of pay of any individual appointed under subsection (a); and

"(B) for purposes of retaining qualified employees, the annual rate of pay for any qualified scientific, technical, or professional personnel appointed to a position described in subsection (a) before the date of enactment of this section.

"(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code.

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

"(c) RULE OF CONSTRUCTION.—The authorities under this section shall not be construed to affect the authority provided under section 714.

"(d) REPORT ON WORKFORCE PLANNING.—

"(1) IN GENERAL.—Not later than 18 months after the date of enactment of the FDA and NIH Workforce Authorities Modernization Act , the Secretary shall submit a report on workforce planning to

the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines the extent to which the Food and Drug Administration has a critical need for qualified individuals for scientific, technical, or professional positions, including—

"(A) an analysis of the workforce needs at the Food and Drug Administration and the Secretary's strategic plan for addressing such needs, including through use of the authority under this section; and

"(B) a recruitment and retention plan for hiring qualified scientific, technical, and professional candidates, which may include the use of—

"(i) recruitment through non-governmental recruitment or placement agencies;

"(ii) recruitment through academic institutions;

"(iii) recruitment or hiring bonuses, if applicable;

"(iv) recruitment using targeted direct hiring authorities; and

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

"(2) RECOMMENDATIONS.—The report under paragraph (1) may include the recommendations of the Commissioner of Food and Drugs that would help the Food and Drug Administration to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.".

(b) GAO STUDY AND REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the ability of the Food and Drug Administration to hire, train, and retain qualified scientific, technical, and professional staff, not including contractors, necessary to fulfill the mission of the Food and Drug Administration to protect and promote public health. Not later than January 1, 2022, the Comptroller General shall submit a report on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

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

(A) information about the progress of the Food and Drug Administration in recruiting and retaining qualified scientific, technical, and professional staff outstanding in the field of biomedical research, clinical research evaluation, and biomedical product assessment;

(B) the extent to which critical staffing needs exist at the Food and Drug Administration, and barriers to hiring, training, and retaining qualified staff, if any;

(C) an examination of the recruitment and retention strategies of the Food and Drug Administration, including examining any strategic workforce plan, focused on improving scientific, technical, and professional staff recruitment and retention; and

(D) recommendations for potential improvements that would address staffing needs of the Food and Drug Administration.

SEC. 4. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

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

"SEC. 1014. FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

"(a) IN GENERAL.—The Secretary shall establish one or more Intercenter Institutes within the Food and Drug Administration (referred to in this section as an 'Institute') for a major disease area or areas. With respect to the major disease area of focus of an Institute, such Institute shall develop and implement processes for coordination of activities, as applicable to such major disease area or areas, between the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health (for the purposes of this section, referred to as the 'Centers'). Such activities may include—

"(1) coordination of staff from the Centers with diverse product expertise in the diagnosis, cure, mitigation, treatment, or prevention of the specific diseases relevant to the major disease area of focus of the Institute;

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

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

"(3) promotion of scientific programs within the Centers related to the major disease area of focus of the Institute;

"(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;

"(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and

"(6) facilitation of the collaborative relationships of the Centers with other agencies within the Department of Health and Human Services regarding the major disease area of focus of the Institute.

"(b) PUBLIC PROCESS.—The Secretary shall provide a period for public comment during the time that each Institute is being implemented.

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

"(d) TERMINATION OF INSTITUTES.—The Secretary may terminate any Institute established pursuant to this section if the Secretary determines such Institute is no longer benefitting the public health. Not less than 60 days prior to so terminating an Institute, the Secretary shall provide public notice, including the rationale for such termination.".

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

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

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

SEC. 5. SCIENTIFIC MEETINGS.

(a) IN GENERAL.—Scientific meetings that are attended by scientific or medical personnel, or other profes-

sionals, of the Department of Health and Human Services for whom attendance at such meeting is directly related to their professional duties and the mission of the Department—

(1) shall not be considered conferences for the purposes of complying with Federal reporting requirements contained in annual appropriations Acts or in this section; and

(2) shall not be considered conferences for purposes of a restriction contained in an annual appropriations Act, based on Office of Management and Budget Memorandum M-12-12 or any other regulation restricting such travel.

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

(c) REPORTS.—Each operating division of the Department of Health and Human Services shall prepare, and post on an Internet website of the operating division, an annual report on scientific meeting attendance and related travel spending for each fiscal year. Such report shall include—

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

(2) information concerning the total amount expended for such meetings;

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

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

(B) the location of such meeting;

(C) the date of such meeting;

(D) a brief explanation on how such meeting advanced the mission of the operating division; and

(E) the total number of individuals whose travel expenses or other scientific meeting expenses were paid by the operating division; and

(4) with respect to any such meeting where the total expenses to the operating division exceeded $150,000, a description of the exceptional circumstances that necessitated the expenditure of such amounts.

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

(a) BOARD OF DIRECTORS.—

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

(A) by redesignating clause (ii) as clause (iii);

(B) by inserting after clause (i) the following:

"(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by

such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries.''; and

(C) in clause (iii)(I), as redesignated by subparagraph (A), by striking ''The ex officio members shall ensure'' and inserting ''The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure''.

(2) FEDERAL EMPLOYEES ALLOWED TO SERVE ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)), as redesignated by paragraph (1)(A), is amended by adding at the end the following: ''For purposes of this section, the term 'employee of the Federal Government' does not include a 'special Government employee', as that term is defined in section 202(a) of title 18, United States Code.''.

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

''(A) TERM.—The term of office of each member of the Board appointed under para-

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

"(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members; and

"(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.".

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

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

grammatic funds under subsection (i), according to best accounting practices''.

SEC. 7. NIH RESEARCH INFORMATION COLLECTION EXEMPTED FROM PAPERWORK REDUCTION ACT.

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

''(f) PAPERWORK REDUCTION.—Subchapter I of chapter 35 of title 44, United States Code, shall not apply to the collection of information during the conduct of research by the National Institutes of Health.''.

SEC. 8. STUDIES.

The Federal Food, Drug, and Cosmetic Act is amended—

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

(A) in subparagraph (A), by inserting ''and'' after the semicolon;

(B) by striking subparagraph (B); and

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

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

(3) in section 505B (21 U.S.C. 355c)—

(A) by striking subsection (l); and

(B) by redesignating subsection (m) as subsection (l); and

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

SEC. 9. SUMMARY LEVEL REVIEW.

Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended by adding at the end the following:

"(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b) or section 351(a) of the Public Health Service Act, if such supplemental application complies with subparagraph (B).

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

"(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

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

"(C) In this paragraph—

"(i) the term 'qualified indication' means an indication for a drug that the Secretary de-

termines to be appropriate for summary level review under this paragraph; and

"(ii) the term 'qualified data summary' means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.".

SEC. 10. DRUG SURVEILLANCE.

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

(1) in subparagraph (A), by striking ", bi-weekly screening" and inserting "screenings";

(2) in subparagraph (B), as redesignated by section 8(1)(C), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(C) make available on the Internet website of the Food and Drug Administration—

"(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the FDA Adverse Event Reporting Systems; and

"(ii) criteria for public posting of adverse event signals.".

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

(c) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505–1(f)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)(5)) is amended—

(1) in the matter preceding subparagraph (A), by inserting "or other advisory committee" after "(or successor committee)"; and

(2) in subparagraph (B), by striking "at least annually," and inserting "periodically".

SEC. 11. BIOLOGICAL PRODUCT INNOVATION.

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

"(1) a product for which a license has been approved under this section shall not be required to have an approved application under section 505 of such Act; and

"(2) those provisions of the Federal Food, Drug, and Cosmetic Act that refer to an official compendium as defined under section 201(j) of such Act shall not apply to a biological product subject to regulation under this section.".

SEC. 12. EXPANDED ACCESS POLICY.

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

"SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.

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

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

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

"(c) CONTENT OF POLICY.—A policy described in subsection (a) shall include—

"(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

"(2) procedures for making such requests;

"(3) the general criteria the manufacturer or distributor will use to evaluate such requests for individual patients, and for responses to such requests; and

"(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests.

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

"(e) REVISED POLICY.—Nothing in this section shall prevent a manufacturer or distributor from revising a policy required under this section at any time.

"(f) APPLICATION.—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the later of—

"(1) the date that is 60 calendar days after the date of enactment of the FDA and NIH Workforce Authorities Modernization Act; or

"(2) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational drug.".

SEC. 13. FINALIZING DRAFT GUIDANCE ON EXPANDED ACCESS.

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

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

SEC. 14. AMENDMENTS TO THE ORPHAN DRUG ACT.

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

(1) in subsection (a), by striking paragraph (1) and inserting the following: "(1) defraying the costs of developing drugs for rare diseases or conditions, including qualified testing expenses,"; and

(2) in subsection (b)(1)—

(A) in subparagraph (A)(ii), by striking "and" after the semicolon;

(B) in subparagraph (B), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(C) prospectively planned and designed observational studies and other analyses conducted to assist in the understanding of the natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to—

"(i) develop or validate a drug development tool related to a rare disease or condition; or

"(ii) understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct

subpopulations affected by a rare disease or condition.".

SEC. 15. STANDARDS FOR REGENERATIVE MEDICINE AND ADVANCED THERAPIES.

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

"SEC. 506G. STANDARDS FOR REGENERATIVE MEDICINE AND ADVANCED THERAPIES.

"(a) IN GENERAL.—The Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordinate and prioritize the development of standards, through a transparent public process, that will help support product development, evaluation, and review, with respect to regenerative medicine and advanced therapies, through regulatory predictability, including with regard to manufacturing processes and controls for regenerative medicine and advanced therapies products.

"(b) ACTIVITIES.—

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

"(A) identify opportunities to help advance the development of regenerative medicine and advanced therapies;

"(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative medicine and advanced therapies through regulatory predictability; and

"(C) work with stakeholders, such as those described in subsection (a), as appropriate, in the development of such standards.

"(2) REGULATIONS AND GUIDANCE.—After the development of standards as described in subsection (a), the Secretary shall review relevant regulations and guidance and, through a transparent public process, update such regulations and guidance as the Secretary determines appropriate.

"(c) DEFINITION.—For purposes of this section, the term 'regenerative medicine and advanced therapies' includes cell therapy, gene therapy, gene-modified cell therapy, therapeutic tissue engineering products, human cell

and tissue products, and combination products using any such therapies or products.''.

SEC. 16. GOOD GUIDANCE PRACTICES.

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

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

(2) by adding at the end the following:

''(iii) When proposing or finalizing any guidance document under this subparagraph, the Secretary shall include in the guidance document a statement, the contents of which are committed to the discretion of the Secretary—

''(I) explaining why the interpretation or policy set forth in such guidance document is being provided in a nonbinding guidance document and not established through rulemaking; and

''(II) identifying each specific statutory provision or regulation being interpreted in the guidance document

or authorizing a policy decision described in the guidance document.".

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

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

Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

"(f) DETERMINATION WITH RESPECT TO PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.—

"(1) DETERMINATION.—If the Secretary determines, after consultation with such public health officials as may be necessary, that—

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

"(ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and

"(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44, United States Code (commonly referred to as the Paperwork Reduction Act);

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate post-response review regarding such public health emergency if such immediate post-response review does not exceed a reasonable length of time.

"(2) TRANSPARENCY.—If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet

website of the Department of Health and Human Services a brief justification for such waiver, the anticipated period of time such waiver will be in effect, and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

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

"(4) TERMINATION OF WAIVER.—Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

"(5) LIMITATIONS.—

"(A) PERIOD OF WAIVER.—The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate post-response review regarding the pub-

lic health emergency consistent with the requirements of this subsection.

"(B) SUBSEQUENT COMPLIANCE.—An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44, United States Code, and the Secretary shall ensure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.".

SEC. 18. TECHNICAL CORRECTIONS.

(a) REFERENCES.—Except as otherwise expressly provided, whenever in this subsection an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) AMENDMENTS.—

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

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

(A) in subsection (d), in the last sentence, by striking "premarket approval" and inserting "marketing approval"; and

(B) in subsection (q)(5)(A), by striking "subsection (b)(2) or (j) of the Act or 351(k)" and inserting "subsection (b)(2) or (j) of this section or section 351(k)".

(3) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505–1(h) of the Act (21 U.S.C. 355–1(h)) is amended—

(A) in paragraph (2)(A)(iii)—

(i) in the clause heading, by striking "LABEL" and inserting "LABELING";

(ii) by striking "label" each place the term appears and inserting "labeling"; and

(iii) by striking "sponsor" and inserting "responsible person"; and

(B) in paragraph (8), by striking "and (7)." and inserting "and (7)".

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

(A) in subsection (e)—

(i) in paragraph (2)—

(I) in subparagraph (A), in the matter preceding clause (i), by inserting "study" after "initial pediatric" each place the term appears; and

(II) in subparagraph (B), in the subparagraph heading, by striking "INITIAL PLAN" and inserting "INITIAL PEDIATRIC STUDY PLAN";

(ii) in paragraph (5), by inserting "AGREED INITIAL PEDIATRIC STUDY" before "PLAN" in the paragraph heading; and

(iii) in paragraph (6), by striking "agreed initial pediatric plan" and inserting "agreed initial pediatric study plan"; and

(B) in subsection (f)(1), by inserting "and any significant amendments to such plans," after "agreed initial pediatric study plans,".

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

(A) in subsection (c), by striking "discontinuation" and inserting "discontinuance"; and

(B) in subsection (g)(1), by striking "section 505(j) that could help" and inserting "section 505(j), that could help".

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

(A) by striking "Not later than the end of calendar year 2013, and not later than the end of each calendar year thereafter," and inserting "Not later than March 31 of each calendar year,"; and

(B) by inserting ", with respect to the preceding calendar year," after "a report".

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

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

(A) in paragraph (4), in the matter preceding subparagraph (A), by striking "establishing the risk-based scheduled" and inserting "establishing a risk-based schedule"; and

(B) in paragraph (6)—

(i) in subparagraph (A), by striking "fiscal" and inserting "calendar" each place the term appears; and

(ii) in subparagraph (B), by striking "an active ingredient of a drug, a finished drug product, or an excipient of a drug" and inserting "an active ingredient of a drug or a finished drug product".

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

(A) in clause (i), by striking "within 30 days"; and

(B) in clause (iv), by striking "low-moderate" and inserting "low to moderate".

(10) PREMARKET APPROVAL.—Section 515(a)(1) of the Act (21 U.S.C. 360e(a)(1)) is amended by striking "subject to a an order" and inserting "subject to an order".

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

(A) by striking subsection (c); and

(B) by redesignating subsection (d) as subsection (c).

(12) UNIQUE DEVICE IDENTIFIER.—Section 519(f) of the Act (21 U.S.C. 360i(f)) is amended by striking "and life sustaining" and inserting "or life sustaining".

(13) PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.—Section 524A of the Act (21 U.S.C. 360n–1) is amended—

(A) by striking "If the Secretary" and inserting the following:

"(a) IN GENERAL.—If the Secretary";

(B) by striking "any" and inserting "the first"; and

(C) by adding at the end the following:

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

(14) CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.—Section 569(a)(2)(A) of the Act (21 U.S.C. 360bbb–8(a)(2)(A)) is amended, in the first sentence, by striking "subsection (c)" and inserting "subsection (b)".

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

(16) USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.—Section 569B of the Act (21 U.S.C. 360bbb–8b) is amended by striking "drug or device" and inserting "drug, biological product, or device" each place the term appears.

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

(A) by inserting "for a new drug" after "any period of exclusivity"; and

(B) by inserting "or any period of exclusivity for a new animal drug under section 512(c)(2)(F)," after "section 505A,".

(18) REGULATION OF MEDICAL GASES.—Section 576(a) of the Act (21 U.S.C. 360ddd–1(a)) is amended—

(A) in the matter preceding subparagraph (A) of paragraph (1), by inserting "who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce" after "any person"; and

(B) in paragraph (3)—

(i) in subparagraph (A)—

(I) in clause (i)(VIII), by inserting "for a new drug" after "any period of exclusivity"; and

(II) in clause (ii), in the matter preceding subclause (I), by inserting "the" before "final use"; and

(ii) in subparagraph (B)—

(I) in clause (i), by inserting "for a new drug" after "any period of exclusivity"; and

(II) in clause (ii), by inserting a comma after "drug product".

(19) INAPPLICABILITY OF DRUG FEES TO DESIGNATED MEDICAL GASES.—Section 577 of this Act (21 U.S.C. 360ddd–2) is amended by inserting "or 740(a)" after "section 736(a)".

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

(21) AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.—Section

744H(a) of the Act (21 U.S.C. 379j–52(a)) is amended—

(A) in paragraph (1)(A)(v), by striking "Biosimilars User Fee Act of 2012" and inserting "Biosimilar User Fee Act of 2012"; and

(B) in paragraph (2)(B), by striking "Biosimilars User Fee Act of 2012" and inserting "Biosimilar User Fee Act of 2012".

(22) REGISTRATION OF COMMERCIAL IMPORTERS.—

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

"(D) EFFECTIVE DATE.—In establishing the effective date of the regulations under subparagraph (A), the Secretary shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.".

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

(23) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809(a)(2) of the Act (21 U.S.C. 384e(a)(2)) is amended by striking "conduction" and inserting "conducting".

(24) FINDINGS RELATING TO DRUG APPROVAL.—Section 901(a)(1)(A) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 21 U.S.C. 356 note) is amended by striking "serious and life-threatening diseases" and inserting "serious or life-threatening diseases".

(25) REPORTING OF INCLUSION OF DEMOGRAPHIC SUBGROUPS.—Section 907 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1092, 1093) is amended—

*(A) in the section heading, by striking "**BIOLOGICS**" in the heading and inserting "**BIOLOGICAL PRODUCTS**"; and*

(B) in subsection (a)(2)(B), by striking "applications for new drug applications" and inserting "new drug applications".

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

(A) in subsection (a)(2), by striking "dependance" and inserting "dependence"; and

(B) in subsection (c), by striking "promulgate" and inserting "issue".

Calendar No. 427

114TH CONGRESS
2D SESSION

S. 2700

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