

Appendices

Appendix A: Legal Mandates for this Report

Pub. L. No. 109-482: The National Institutes of Health Reform Act of 2006 (Relevant Provisions)

An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, 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 "National Institutes of Health Reform Act of 2006".

TITLE I—NIH REFORM

SEC. 102. AUTHORITY OF DIRECTOR OF NIH.

(b) ADDITIONAL AUTHORITIES.—Section 402(b) of the Public Health Service Act, as amended by subsection (a) of this section, is amended by striking paragraphs (2) and (3) and inserting the following:

(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

“ (i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning;

“(ii) include information on such research in reports under section 403;

SEC. 104. REPORTS

(a) REPORT OF DIRECTOR OF NIH.—The Public Health Service Act (42 U.S.C. 201 et seq.), as amended by section 103(a) of this Act, is amended—

(3) by striking section 403 <<NOTE: 42 USC 283.>> and inserting the following sections:

“SEC. 403. BIENNIAL REPORTS OF DIRECTOR OF NIH.

“(a) IN GENERAL.—The Director of NIH shall submit to the Congress on a biennial basis a report in accordance with this section. The first report shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006. Each such report shall include the following information:

“(1) An assessment of the state of biomedical and behavioral research.

“(2) A description of the activities conducted or supported by the agencies of the National Institutes of Health and policies respecting the programs of such agencies.

“(3) Classification and justification for the priorities established by the agencies, including a strategic plan and recommendations for future research initiatives to be carried out under section 402(b)(7) through the Division of Program Coordination, Planning, and Strategic Initiatives.

“(4) A catalog of all the research activities of the agencies, prepared in accordance with the following:

“(A) The catalog shall, for each such activity—

“(i) identify the agency or agencies involved;

“(ii) state whether the activity was carried out directly by the agencies or was supported by the agencies and describe to what extent the agency was involved; and

“(iii) identify whether the activity was carried out through a center of excellence.

“(B) In the case of clinical research, the catalog shall, as appropriate, identify study populations by demographic variables and other variables that contribute to research on minority health and health disparities.

“(C) Research activities listed in the catalog shall include, where applicable, the following:

“(i) Epidemiological studies and longitudinal studies.

“(ii) Disease registries, information clearinghouses, and other data systems.

“(iii) Public education and information campaigns.

“(iv) Training activities, including—

“(I) National Research Service Awards and Clinical Transformation Science Awards;

“(II) graduate medical education programs, including information on the number and type of graduate degrees awarded during the period in which the programs received funding under this title;

“(III) investigator-initiated awards for postdoctoral training;

“(IV) a breakdown by demographic variables and other appropriate categories; and

“(V) an evaluation and comparison of outcomes and effectiveness of various training programs.

“(v) Clinical trials, including a breakdown of participation by study populations and demographic variables and such other information as may be necessary to demonstrate compliance with section 492B (regarding inclusion of women and minorities in clinical research).

“(vi) Translational research activities with other agencies of the Public Health Service.

“(5) A summary of the research activities throughout the agencies, which summary shall be organized by the following categories, where applicable:

“(A) Cancer.

“(B) Neurosciences.

“(C) Life stages, human development, and rehabilitation.

“(D) Organ systems.

“(E) Autoimmune diseases.

“(F) Genomics.

“(G) Molecular biology and basic science.

“(H) Technology development.

“(I) Chronic diseases, including pain and palliative care.

“(J) Infectious diseases and bioterrorism.

“(K) Minority health and health disparities.

“(L) Such additional categories as the Director determines to be appropriate.

“(6) A review of each entity receiving funding under this title in its capacity as a center of excellence (in this paragraph referred to as a ‘center of excellence’), including the following:

“(A) An evaluation of the performance and research outcomes of each center of excellence.

“(B) Recommendations for promoting coordination of information among the centers of excellence.

“(C) Recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

“(D) If no additional centers of excellence have been funded under this title since the previous report under this section, an explanation of the reasons for not funding any additional centers.

“(b) Requirement Regarding Disease-Specific Research Activities.— In a report under subsection (a), the Director of NIH, when reporting on research activities relating to a specific disease, disorder, or other adverse health condition, shall—

“(1) present information in a standardized format;

“(2) identify the actual dollar amounts obligated for such activities; and

“(3) include a plan for research on the specific disease, disorder, or other adverse health condition, including a statement of objectives regarding the research, the means for achieving the objectives, a date by which the objectives are expected to be achieved, and justifications for revisions to the plan.

SEC. 106. ENHANCING THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD.

(a) IN GENERAL.—In administering the Clinical and Translational Science Award, the Director of NIH shall establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers by—

(b) REPORT.—As part of the biennial report under section 403 of the Public Health Service Act, the Director of NIH shall provide an evaluation and comparison of outcomes and effectiveness of training programs under subsection (a)

Public Law 110-85: The Food and Drug Administration Act of 2007 (Relevant Provisions)

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the post market authorities of the Food and Drug Administration with respect to the safety of drugs, 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 "Food and Drug Administration Amendments Act of 2007."

TITLE XI—OTHER PROVISIONS

Subtitle A—In General

SEC. 1104. NIH TECHNICAL AMENDMENTS.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

- (3) in section 403(a)(4)(C)(iv)(III), by inserting "and postdoctoral training funded through research grants" before the semicolon;

Public Law 110-204: The Newborn Screening Saves Lives Act of 2007 (Relevant Provisions)

An Act

To amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated follow-up once newborn screening has been conducted, to reauthorize programs under part A of title XI of such Act, 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 "Newborn Screening Saves Lives Act of 2007."

SECTION 7. CONTINGENCY PLANNING.

Part A of title XI of the Public Health Service Act (42 U.S.S. 300b-1 et seq.) as amended by section 6, is further amended by adding at the end the following:

“SEC. 1116. HUNTER KELLY RESEARCH PROGRAM.

(a) NEWBORN SCREENING ACTIVITIES.—

“(1) IN GENERAL.—The Secretary , in conjunction with the Director of the National Institutes of Health and taking into consideration the recommendations of the Advisory Committee, may continue carrying out, coordinating, and expanding research in newborn screening (to be known as ‘Hunter Kelly Newborn Screening Research Program’) including —

“(c) REPORTS.— The Director is encouraged to include information about the activities carried out under this section in the biennial report required under section 403 of the National Institutes of Health Reform Act of 2006.