

# **Appendix A: Authorizing Legislation**

Public Law 108-154  
108th Congress

An Act

To revise and extend the Birth Defects Prevention Act of 1998.

Dec. 3, 2003

[S. 286]

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

Birth Defects and  
Developmental  
Disabilities  
Prevention Act of  
2003.  
42 USC 201 note.

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Birth Defects and Developmental Disabilities Prevention Act of 2003”.

**SEC. 2. NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES.**

Section 317C of the Public Health Service Act (42 U.S.C. 247b-4) is amended—

(1) in subsection (a)(2)—

(A) in subparagraph (A)—

(i) by striking “and developmental disabilities” and inserting “, developmental disabilities, and disabilities and health”; and

(ii) by striking “subsection (d)(2)” and inserting “subsection (c)(2)”;

(B) in subparagraph (B), by striking “and” at the end;

(C) in subparagraph (C), by striking the period and inserting a semicolon; and

(D) by adding at the end the following:

“(D) to conduct research on and to promote the prevention of such defects and disabilities, and secondary health conditions among individuals with disabilities; and

“(E) to support a National Spina Bifida Program to prevent and reduce suffering from the Nation’s most common permanently disabling birth defect.”;

(2) by striking subsection (b);

(3) in subsection (d)—

(A) by striking paragraph (1) and inserting the following:

“(1) contains information regarding the incidence and prevalence of birth defects, developmental disabilities, and the health status of individuals with disabilities and the extent to which these conditions have contributed to the incidence and prevalence of infant mortality and affected quality of life;”;

(B) in paragraph (3), by inserting “, developmental disabilities, and secondary health conditions among individuals with disabilities” after “defects”;

(C) in paragraph (4), by striking “and” at the end;

(D) by redesignating paragraph (5) as paragraph (7);

and

(E) by inserting after paragraph (4) the following:

“(5) contains information on the incidence and prevalence of individuals living with birth defects and disabilities or developmental disabilities, information on the health status of individuals with disabilities, information on any health disparities experienced by such individuals, and recommendations for improving the health and wellness and quality of life of such individuals;

“(6) contains a summary of recommendations from all birth defects research conferences sponsored by the Centers for Disease Control and Prevention, including conferences related to spina bifida; and”;

(4) by redesignating subsections (c), (d), and (e) as subsections (b), (c), and (d), respectively;

(5) by inserting after subsection (d) (as so redesignated), the following:

“(e) **ADVISORY COMMITTEE.**—Notwithstanding any other provision of law, the members of the advisory committee appointed by the Director of the National Center for Environmental Health that have expertise in birth defects, developmental disabilities, and disabilities and health shall be transferred to and shall advise the National Center on Birth Defects and Developmental Disabilities effective on the date of enactment of the Birth Defects and Developmental Disabilities Prevention Act of 2003.”; and

(6) in subsection (f), by striking “\$30,000,000” and all that follows and inserting “such sums as may be necessary for each of fiscal years 2003 through 2007.”.

### **SEC. 3. TECHNICAL CORRECTIONS FOR STATE COUNCILS ON DEVELOPMENTAL DISABILITIES.**

(a) **IN GENERAL.**—Section 122(a) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15022(a)) is amended—

(1) in paragraph (3)(A)(ii), by inserting before the period the following: “, the amount received by the State for the previous year, or the amount of Federal appropriations received in fiscal year 2000, 2001, or 2002, whichever is greater”; and

(2) in paragraph (4)(A)(ii), by inserting before the period the following: “, the amount received by the State for the previous year, or the amount of Federal appropriations received in fiscal year 2000, 2001, or 2002, whichever is greater”.

(b) **EFFECTIVE DATE.**—The amendments made by subsection (a) shall take effect on October 1, 2003 and apply to allotments beginning in fiscal year 2004.

### **SEC. 4. REPORT ON SURVEILLANCE ACTIVITIES.**

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services jointly with the Secretary of Education shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce and Committee on Education and the Workforce of the House of Representatives a report concerning surveillance activities under section 102 of the Children’s Health Act of 2000 (Public Law 106-310), specifically including—

(1) a description of the current grantees under the National Autism and Pervasive Developmental Disabilities Surveillance Program and the Centers of Excellence in Autism and Pervasive Developmental Disabilities, the data collected, analyzed, and

Applicability.  
42 USC 15022  
note.

Deadline.  
42 USC 247b-4b  
note.

reported under such grants, the sources of such data, and whether such data was obtained with parental consent as required under the Family Educational Rights and Privacy Act of 1974 (20 U.S.C. 1232g);

(2) a description of current sources of data for the surveillance of autism and developmental disabilities and the methods for obtaining such data, including whether such data was obtained with parental or patient consent for disclosure;

(3) an analysis of research on autism and developmental disabilities with respect to the methods of collection and reporting, including whether such research was obtained with parental or patient consent for disclosure;

(4) an analysis of the need to add education records in the surveillance of autism and other developmental disabilities, including the methodological and medical necessity for such records and the rights of parents and patients in the use of education records (in accordance with the Family Educational Rights and Privacy Act of 1974);

(5) a description of the efforts taken by the Centers for Disease Control and Prevention to utilize education records in conducting the surveillance program while obtaining parental or patient consent for such education records, including the outcomes of such efforts;

(6) a description of the challenges provided to obtaining education records (in the absence of parental or patient consent) for the purpose of obtaining additional surveillance data for autism and other developmental disabilities; and

(7) a description of the manner in which such challenges can be overcome, including efforts to educate parents, increase confidence in the privacy of the surveillance program, and increase the rate of parental or patient consent, and including specific quantitative and qualitative justifications for any recommendations for changes to existing statutory authority, including the Family Educational Rights and Privacy Act of 1974.

## SEAS AND DUTIES OF PUBLIC SERVICE

### AND INVESTIGATION

#### FEDERAL

shall conduct in the Service, and render assistance to other appropriate institutions, and scientists in coordination of, research, investigations, and studies relating to the control, and prevention of physical pollution of lakes and streams. In the event that the Secretary is authorized to—

publish through publications and reports information as to, and the practical application of, and other activities;

use the facilities of the Service to appoint and to health officials and scientists;

use, in universities, hospitals, laboratories, and other institutions, and to individuals, as are recommended by the advisory committee of the Department supporting such recommendations of the advisory committee of the Department, grants-in-aid for the maintenance of laboratories, and other support of their research; and to provide for such periods as he may determine and in the name and on the advice of experts, scholars, and other persons in the United States or abroad;

admit and treat at institutions, and other persons not otherwise eligible;

use health officials, scientists, and other persons in nonprofit institutions and organizations, and assistance on the application of statistics, studies, and surveys in health

including contracts for research in the field of the provisions of law applicable to the military departments under sections 2353 and 2354, except that the Secretary may, in the name and certification required therefor, Health, Education, and Welfare;

54

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b)(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains—

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient,

established by a Federal agent, or exposure standard established with respect to a substance contained in paragraph (A), the extent to which, scientific, or other data, such as the condition of such standard by the public health from exposure to

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to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts.

(b) The Surgeon General shall cooperate with States for the purpose of aiding them to solve their narcotic drug problems and shall give authorized representatives of the States the benefit of his experience in the care, treatment, and rehabilitation of narcotic addicts to the end that each State may be encouraged to provide adequate facilities and methods for the care and treatment of its narcotic addicts.

GENERAL AUTHORITY RESPECTING RESEARCH, EVALUATIONS, AND DEMONSTRATIONS IN HEALTH STATISTICS, HEALTH SERVICES, AND HEALTH CARE TECHNOLOGY ASSESSMENT

SEC. 304. <sup>1</sup> [242b] (a) The Secretary may, through the Agency for Health Care Policy and Research or the National Center for Health Statistics or using National Research Service Awards or other appropriate authorities, undertake and support training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects set forth in section 306 and in title IX.

(b) To implement subsection (a) and section 306, the Secretary may, in addition to any other authority which under other provisions of this Act or any other law may be used by him to implement such subsection, do the following:

(1) Utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, provide technical assistance and advice, make grants to public and nonprofit private entities and individuals, and, when appropriate, enter into contracts with public and private entities and individuals.

(2) Admit and treat at hospitals and other facilities of the Service persons not otherwise eligible for admission and treatment at such facilities.

(3) Secure, from time to time and for such periods as the Secretary deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad. The Secretary may for the purpose of carrying out the functions set forth in sections 305, <sup>2</sup> 306, and 309, obtain (in accordance with section 3109 of title 5 of the United States Code, but without regard to the limitation in such section on the number of days or the period of service) for each of the centers the services of not more than fifteen experts who have appropriate scientific or professional qualifications.

<sup>1</sup>Former section 303 was repealed by section 3201(b)(1) of Public Law 106-310 (114 Stat. 1190).

<sup>2</sup>See footnote for section 306.

entation plan for pro-  
 financial assistance for ac-  
 on of lead poisoning;  
 m for sharing and dis-  
 ong the agencies rep-

missing areas of research  
 poisoning;  
 and technological con-

soning prevention;  
 comprehensive review of

assistance to prevent lead  
 May 1 of each year, sub-

or and Human Resources  
 ittee on the Environment

ate, and to the Committee

the House of Representa-

zed the findings made as

orce on the programs and

h the Task Force is estab-

udgetary recommendations;

d coordinate departmental  
 sts with respect to all lead  
 es of the Federal Govern-

EPIDEMIOLOGY.—The Sec-  
 e Centers for Disease Con-  
 ough grants or contracts—  
 of improved, more cost-ef-  
 g lead toxicity in children;  
 of improved methods of as-  
 ning, including such meth-  
 individual assessments for

data on the incidence and  
 nts and children, on the de-  
 e and children with such  
 thnic status), and on the  
 r such poisoning (including  
 s paid for such treatment);

earch necessary to improve  
 the prevention of lead poi-

ITS AND DEVELOPMENTAL

l.—

e is established within the  
 Prevention a center to be  
 Birth Defects and Develop-  
 this section as the "Center"),

which shall be headed by a director appointed by the Director  
 of the Centers for Disease Control and Prevention.

(2) GENERAL DUTIES.—The Secretary shall carry out  
 programs—

(A) to collect, analyze, and make available data on  
 birth defects and developmental disabilities (in a manner  
 that facilitates compliance with subsection (d)(2)), includ-  
 ing data on the causes of such defects and disabilities and  
 on the incidence and prevalence of such defects and dis-  
 abilities;

(B) to operate regional centers for the conduct of ap-  
 plied epidemiological research on the prevention of such  
 defects and disabilities; and

(C) to provide information and education to the public  
 on the prevention of such defects and disabilities.

(3) FOLIC ACID.—The Secretary shall carry out section  
 317J through the Center.

(4) CERTAIN PROGRAMS.—

(A) TRANSFERS.—All programs and functions described  
 in subparagraph (B) are transferred to the Center, effec-  
 tive upon the expiration of the 180-day period beginning  
 on the date of the enactment of the Children's Health Act  
 of 2000<sup>1</sup>.

(B) RELEVANT PROGRAMS.—The programs and func-  
 tions described in this subparagraph are all programs and  
 functions that—

(i) relate to birth defects; folic acid; cerebral palsy;  
 mental retardation; child development; newborn  
 screening; autism; fragile X syndrome; fetal alcohol  
 syndrome; pediatric genetic disorders; disability pre-  
 vention; or other relevant diseases, disorders, or condi-  
 tions as determined the Secretary; and

(ii) were carried out through the National Center  
 for Environmental Health as of the day before the  
 date of the enactment of the Act referred to in sub-  
 paragraph (A).

(C) RELATED TRANSFERS.—Personnel employed in con-  
 nection with the programs and functions specified in sub-  
 paragraph (B), and amounts available for carrying out the  
 programs and functions, are transferred to the Center, ef-  
 fective upon the expiration of the 180-day period beginning  
 on the date of the enactment of the Act referred to in sub-  
 paragraph (A). Such transfer of amounts does not affect  
 the period of availability of the amounts, or the avail-  
 ability of the amounts with respect to the purposes for  
 which the amounts may be expended.

(b) ADDITIONAL PROVISIONS REGARDING COLLECTION OF  
 DATA.—

(1) IN GENERAL.—In carrying out subsection (a)(2)(A), the  
 Secretary—

(A) shall collect and analyze data by gender and by ra-  
 cial and ethnic group, including Hispanics, non-Hispanic

<sup>1</sup> Public Law 106-310, enacted October 17, 2000.

icans, Asian Americans, and  
 nder subparagraph (A) from  
 ificates, hospital records, and  
 cretary determines to be ap-

s to establish or improve pro-  
 1 analysis of epidemiological  
 make the data available.

.—In carrying out subsection  
 ish and maintain a National  
 th Defects to collect and dis-  
 and the general public infor-  
 g the prevention of such de-

g out subsection (a), the Sec-  
 nter into contracts with public

#### IN LIEU OF AWARD FUNDS.—

a recipient of an award of a  
 graph (1), the Secretary may,  
 , provide supplies, equipment,  
 of aiding the recipient in car-  
 which the award is made and,  
 ail to the recipient any officer  
 ment of Health and Human  
 request described in subpara-  
 shall reduce the amount of pay-  
 volved by an amount equal to  
 nnel and the fair market value  
 , or services provided by the  
 hall, for the payment of ex-  
 ng with such request, expend

—The Secretary may make an  
 nder paragraph (1) only if an ap-  
 mitted to the Secretary and the  
 nmade in such manner, and con-  
 ces, and information as the Sec-  
 rry to carry out the purposes for

r than February 1 of fiscal year  
 thereafter, the Secretary shall  
 rce of the House of Representa-  
 and Human Resources of the  
 o the preceding 2 fiscal years—  
 regarding the incidence and prev-  
 e extent to which birth defects  
 ce and prevalence of infant mor-

nder paragraph (1) that is spe-  
 ic groups (including Hispanics

non-Hispanic whites, Blacks, Native Americans, and Asian  
 Americans);

(3) contains an assessment of the extent to which various  
 approaches of preventing birth defects have been effective;

(4) describes the activities carried out under this section;

and (5) contains any recommendations of the Secretary regard-  
 ing this section.

(e) **APPLICABILITY OF PRIVACY LAWS.**—The provisions of this  
 section shall be subject to the requirements of section 552a of title  
 5, United States Code. All Federal laws relating to the privacy of  
 information shall apply to the data and information that is col-  
 lected under this section.

(f) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of  
 carrying out this section, there are authorized to be appropriated  
 \$30,000,000 for fiscal year 1999, \$40,000,000 for fiscal year 2000,  
 and such sums as may be necessary for each of the fiscal years  
 2001 and 2002.

#### PREVENTIVE HEALTH MEASURES WITH RESPECT TO PROSTATE CANCER

**SEC. 317D. [247b-5] (a) IN GENERAL.**—The Secretary, acting  
 through the Director of the Centers for Disease Control and Pre-  
 vention, may make grants to States and local health departments  
 for the purpose of enabling such States and departments to carry  
 out programs that may include the following:

(1) To identify factors that influence the attitudes or levels  
 of awareness of men and health care practitioners regarding  
 screening for prostate cancer.

(2) To evaluate, in consultation with the Agency for Health  
 Care Policy and Research and the National Institutes of  
 Health, the effectiveness of screening strategies for prostate  
 cancer.

(3) To identify, in consultation with the Agency for Health  
 Care Policy and Research, issues related to the quality of life  
 for men after prostate cancer screening and followup.

(4) To develop and disseminate public information and  
 education programs for prostate cancer, including appropriate  
 messages about the risks and benefits of prostate cancer  
 screening for the general public, health care providers, policy  
 makers and other appropriate individuals.

(5) To improve surveillance for prostate cancer.

(6) To address the needs of underserved and minority pop-  
 ulations regarding prostate cancer.

(7) Upon a determination by the Secretary, who shall take  
 into consideration recommendations by the United States Pre-  
 ventive Services Task Force and shall seek input, where appro-  
 priate, from professional societies and other private and public  
 entities, that there is sufficient consensus on the effectiveness  
 of prostate cancer screening—

(A) to screen men for prostate cancer as a preventive  
 health measure;

(B) to provide appropriate referrals for the medical  
 treatment of men who have been screened under subpara-  
 graph (A) and to ensure, to the extent practicable, the nec-



