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To amend title XI of the Public Health Service Act to provide for the use of new genetic technologies to meet the health care needs of the public.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 19, 1999

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend title XI of the Public Health Service Act to provide for the use of new genetic technologies to meet the health care needs of the public.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Genetics and Public
5 Health Services Act”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—Congress finds:

8 (1) Genetic disorders comprise a spectrum of
9 diseases caused, entirely or in part, by inherited or
10 acquired mutations in a person’s genes.

1 (2) Included amongst the many genetic diseases
2 are those caused by a single gene mutation, such as
3 Sickle Cell disease, Cystic Fibrosis, and PKU, as
4 well as the more common, multi-factorial “genetic”
5 disorders, such as diabetes, mental illness, heart dis-
6 ease, and cancer.

7 (3) Current estimates are that 1 in 20 individ-
8 uals will be diagnosed with a single gene disorder by
9 the age of 25 and that 65 percent of the population
10 will be diagnosed during their lifetime with a single
11 gene disorder or a disorder that has a genetic com-
12 ponent.

13 (4) Significant public and private resources
14 have been dedicated to genetics research, including
15 the Human Genome Project, leading to marked im-
16 provements in our understanding of and increasing
17 ability to diagnose and treat genetic disorders. From
18 1993 to the present, the number of diagnostic tests
19 available for genetic disorders has increased more
20 than six-fold. The fraction of the population recog-
21 nized as having genetic disorders, including dis-
22 orders with a genetic component, will continue to in-
23 crease dramatically as medical genetics knowledge
24 advances.

1 (5) Research is also leading to an expanding
2 array of available therapies that will result in new
3 treatments for genetic disorders, and may ultimately
4 lead to cures for genetic disorders.

5 (6) There has yet to be a coordinated Federal
6 effort to apply research discoveries in ways that will
7 ensure direct benefit to Americans who are at risk
8 of or living with genetic disorders.

9 (7) Early diagnosis and treatment can lead to
10 prevention of unnecessary human suffering, and con-
11 siderable savings in costs related to treating ad-
12 vanced disease.

13 (8) To ensure that individuals benefit from ge-
14 netic technology and information, it is necessary to
15 ensure the availability of comprehensive genetic serv-
16 ices including education and genetic counseling, ap-
17 propriate genetic evaluation that is preceded by in-
18 formed consent and followed by the opportunity to
19 explore the impact of the results of such evaluation
20 or other tests, and fair access to services for evalua-
21 tion, followup and treatment.

22 (9) The field of genetics is evolving at a great
23 pace. Genetic services will create tremendous poten-
24 tial to improve the lives of patients, but genetic serv-
25 ices that are inappropriately administered may be

1 unnecessary or even harmful. Only a well-informed
2 society, including the health workforce, policy mak-
3 ers, and citizens, can apply and use new discoveries
4 in a fashion that will broadly benefit the public.

5 (10) At present, most States have few available
6 public health genetic services due to limited funding.

7 (11) The Federal Government has historically
8 supported and administered programs that provide
9 nongenetic, essential health services, such as access
10 to vaccinations for children, and require State collec-
11 tion of data on certain diseases. In addition, Federal
12 agencies, including the Centers for Disease Control
13 and Prevention, the Health Resources and Services
14 Administration, and the National Institutes of
15 Health, are working collaboratively to begin to ad-
16 dress the need for genetic services.

17 (12) Without additional Federal support and
18 agency oversight, however, States lack the resources
19 needed to deal adequately with the expanding ge-
20 netic technologies. A new commitment to genetic
21 services should build upon existing programs and
22 provide for the establishment and support of new
23 and innovative programs.

1 (b) PURPOSE.—It is the purpose of this Act to pro-
2 vide for the establishment of genetic grant programs to
3 enable each State and territory to—

4 (1) establish, expand, and maintain systems
5 and programs to provide quality genetic information,
6 counseling, testing and specialty services necessary
7 to preserve public and personal health and welfare;

8 (2) initiate and promote programs and services
9 to reduce the mortality and the morbidity for heri-
10 table disorders and to reduce the adverse effects on
11 mental and physical health of heritable disorders in
12 the population;

13 (3) develop within each State health agency ex-
14 pertise capable of determining needs and level of ge-
15 netic services available, and of assuring the quality,
16 provision and promotion of genetic services required
17 by residents of the State;

18 (4) promote the understanding, by the public
19 and by health care providers, of genetic disorders
20 and their diagnosis, prevention, and treatment, and
21 to provide for a mechanism for public input on State
22 genetic policy and programs;

23 (5) assure that any services provided under this
24 Act shall be available to all individuals, regardless of

1 income, race, color, religion, sex, national origin,
2 age, or disability; and

3 (6) establish the following grant programs:

4 (A) A Federal-State block grant program,
5 with matching funds, to support the establish-
6 ment, expansion and maintenance of State re-
7 sources for public health genetics activities.

8 (B) A grant program to support applied
9 public health research in genetics and projects
10 to develop and test strategies and education
11 programs to use genetic information and tech-
12 nology to improve public health.

13 **SEC. 3. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.**

14 Part A of title XI of the Public Health Service Act
15 (42 U.S.C. 300b–1 et seq.) is amended—

16 (1) by inserting after the part designation the
17 following:

18 **“Subpart I—Grants for Research”**; and

19 (2) by adding at the end the following:

20 **“Subpart II—Genetic Grants**

21 **“SEC. 1110. GRANTS TO STATES.**

22 **“(a) BLOCK GRANTS.—**

23 **“(1) IN GENERAL.—**The Secretary shall award
24 grants to States for the purpose of enabling such

1 States to establish, improve and maintain State pub-
 2 lic health infrastructure for genetics.

3 “(2) ADMINISTRATION.—The Secretary may
 4 provide for the administration of the block grant
 5 program under paragraph (1) through the creation
 6 of an office for genetic services, if the Secretary de-
 7 termines such administration to be appropriate.

8 “(b) GRANTS FOR APPLIED PUBLIC HEALTH RE-
 9 SEARCH AND SYSTEMS DEVELOPMENT.—

10 “(1) IN GENERAL.—The Secretary shall award
 11 grants to eligible entities to carry out studies or to
 12 establish pilot and demonstration public health pro-
 13 grams for the diagnosis and management of genetic
 14 diseases, including diseases with a genetic compo-
 15 nent, education projects for health care providers
 16 and the general public, population studies relating to
 17 genetics, or for other activities of the type described
 18 in subsection (c).

19 “(2) ELIGIBLE ENTITIES.—To be eligible to re-
 20 ceive a grant under paragraph (1) an entity shall—

21 “(A) be a public or nonprofit private enti-
 22 ty, including institutions of higher education;

23 “(B) prepare and submit to the Secretary
 24 an application at such time, in such manner,
 25 and containing such information as the Sec-

retary may require, including whether the activities to be carried out under the grant are easily replicated and the strategies for translating such activities for use in both the public and private sectors; and

“(C) agree to provide regular reports and conduct audits in accordance with subsections (b) and (c) of section 1114.

“(c) USE OF FUNDS.—

“(1) IN GENERAL.—A State shall use amounts provided under a grant under subsection (a) to carry out activities to—

“(A) establish, expand and maintain systems to provide quality genetic information, counseling, testing and specialty services necessary to preserve public and personal health and welfare;

“(B) initiate and promote programs and services to reduce the mortality and the morbidity for heritable disorders and to reduce the adverse effects on mental and physical health of heritable disorders in the population;

“(C) develop within the State health agency expertise capable of determining needs and level of genetic services available, and of assur-

1 ing the quality, provision and promotion of ge-
 2 netic services required by residents of the State;

3 “(D) promote the understanding, by the
 4 public and by health care providers in the
 5 State, of genetic disorders and their prevention
 6 and treatment, and to provide for a mechanism
 7 for public input on State genetic policy and pro-
 8 grams; and

9 “(E) assure that any services provided
 10 under this subpart shall be available to all indi-
 11 viduals, regardless of income, race, color, reli-
 12 gion, sex, national origin, age, or disability.

13 “(2) LIMITATION.—A State may not use funds
 14 received under this section to—

15 “(A) provide cash payments to or on behalf
 16 of affected individuals;

17 “(B) provide inpatient services;

18 “(C) purchase land or make capital im-
 19 provements to property;

20 “(D) meet the matching requirements re-
 21 lating to the receipt of other Federal funds; and

22 “(E) provide for proprietary research or
 23 training.

24 “(d) VOLUNTARY PARTICIPATION.—The participa-
 25 tion by any individual in any program or portion thereof

1 established or operated with funds received under this sub-
 2 part shall be wholly voluntary and shall not be a pre-
 3 requisite to eligibility for or receipt of any other service
 4 or assistance from, or to participation in, any other Fed-
 5 eral or State program.

6 **“SEC. 1111. ADVISORY COMMITTEE.**

7 “(a) ESTABLISHMENT.—The Secretary shall estab-
 8 lish an advisory committee to be known as the ‘Advisory
 9 Committee on Genetics and Public Health Services’ (re-
 10 ferred to in this subpart as the ‘Advisory Committee’).

11 “(b) MEMBERS.—

12 “(1) IN GENERAL.—The Advisory Committee
 13 shall be composed of ex officio members in accord-
 14 ance with paragraph (2) and an odd number of ap-
 15 pointed members, not to exceed 15, in accordance
 16 with paragraph (3).

17 “(2) EX OFFICIO MEMBERS.—The ex officio
 18 members of the Advisory Committee shall include
 19 the Surgeon General, the Administrator of the
 20 Health Resources and Services Administration, the
 21 Director of the Centers for Disease Control and Pre-
 22 vention, and representatives of—

23 “(A) the National Institutes of Health;

24 “(B) the Agency for Health Care Policy
 25 and Research;

1 “(C) the Food and Drug Administration;
2 and

3 “(D) such other agencies and offices within
4 the Department of Health and Human Services,
5 or other Federal agencies, that administer pro-
6 grams dealing with genetics.

7 “(3) APPOINTED MEMBERS.—The appointed
8 members of the Advisory Committee shall be individ-
9 uals appointed by the Secretary to ensure input
10 from—

11 “(A) the various sectors of the clinical ge-
12 netics community that are directly involved in
13 providing clinical services, including clinical lab-
14 oratory services, to the public;

15 “(B) the public, especially regarding con-
16 cerns about access to health care and the risk
17 of genetic discrimination;

18 “(C) the scientific genetic and genetic epi-
19 demiology community;

20 “(D) the private sector; and

21 “(E) State health agencies and the public
22 health community.

23 “(c) DUTIES.—The Advisory Committee shall—

1 “(1) provide advice and recommendations to the
2 Secretary concerning grants and projects awarded or
3 funded under this subpart;

4 “(2) provide technical information to the Sec-
5 retary for the development of policies and priorities
6 for the administration of grants under this subpart;

7 “(3) carry out other activities under this sub-
8 part as determined appropriate by the Secretary;
9 and

10 “(4) submit to Congress an annual report, to be
11 prepared by the Health Resources and Services Ad-
12 ministration together with the Centers for Disease
13 Control and Prevention, concerning the activities
14 under this subpart, including a description of pro-
15 grams that receive funding and objective measures
16 of the effects of such programs on public health.

17 **“SEC. 1112. APPLICATION.**

18 “(a) IN GENERAL.—To be eligible for a block grant
19 under section 1110(a), a State shall prepare and submit
20 to the Secretary an application that includes—

21 “(1) a statewide needs assessment that identi-
22 fies specific health status goals and objectives rel-
23 ative to genetic disorders, including attention to
24 needs of special populations;

1 “(2) a plan for addressing the needs identified
2 in priority order, and the manner in which funds
3 under section 1110(a) will be used to meet the goals
4 and objectives of the State;

5 “(3) a plan for the collection of outcome data
6 or other methods of evaluating the degree to which
7 the funds provided under the grant will be used to
8 achieve the goals and objectives of the State;

9 “(4) a plan for monitoring and ensuring the
10 quality of services provided under the grant, includ-
11 ing attention to issues of access to specialty care;

12 “(5) a plan for the education of the appropriate
13 professional staff of the public health department
14 with respect to genetics, and for increasing the
15 knowledge of health care providers and the general
16 public concerning genetic disease;

17 “(6) an assurance that the State will use funds
18 provided under the grant to supplement and, to the
19 extent practicable, to increase the level of funding
20 that would otherwise be made available by the State
21 for genetic programs and not to supplant such non-
22 Federal funds;

23 “(7) an assurance that the State will provide
24 matching funds in accordance with section 1113(d);

1 “(8) an assurance that funds provided under
2 the grant will only be used to implement the ap-
3 proved plan for the State;

4 “(9) an assurance that the provision of services
5 under the plan is coordinated with services provided
6 under programs implemented in the State under title
7 V, XVIII, XIX, XX, or XXI of the Social Security
8 Act (subject to Federal regulations applicable to
9 such program) so that the coverage of services under
10 such titles is not diminished in any way by the avail-
11 ability of services under a genetic program imple-
12 mented under a grant under section 1110(a) in the
13 State; and

14 “(10) such other information as the Secretary
15 considers appropriate.

16 “(b) PUBLICATION.—An application submitted under
17 this section shall be made public by the State in such a
18 manner as to facilitate comment from any person, includ-
19 ing through hearings and other methods used to facilitate
20 comments from the public. Any such comments received
21 shall be addressed in the application.

22 “(c) MULTISTATE APPLICATIONS.—Two or more
23 States may enter into an agreement to submit a joint
24 multistate application for a single block grant under sec-
25 tion 1110(a) in order to maximize the use of scarce re-

1 gional resources. Any such application shall contain assur-
 2 ances that each State that is a party to the application
 3 will—

4 “(1) be addressed with respect to the require-
 5 ments of paragraphs (1) through (10) of subsection
 6 (a); and

7 “(2) comply with all other provisions of this
 8 subpart.

9 **“SEC. 1113. ALLOCATION OF FUNDS.**

10 “(a) IN GENERAL.—For each fiscal year, the amount
 11 of the grant for each State or territory under section
 12 1110(a) for the fiscal year involved shall be the greater
 13 of—

14 “(1) the amount determined under subsection
 15 (b) for the State or territory for the fiscal year; or

16 “(2) \$400,000.

17 “(b) FORMULA.—With respect to a State or territory,
 18 the amount determined under this subsection shall be
 19 equal to the amount that bears the same ratio to the
 20 amount appropriated for the fiscal year involved under
 21 section 1115 as the population of the State or territory
 22 bears to the population of all States and territories.

23 “(c) REDISTRIBUTION OF CERTAIN FUNDS.—Except
 24 as provided in section 1115(a)(3), any amount appro-

1 priated for a fiscal year under section 1115 and remaining
 2 available as a result of—

3 “(1) the failure of any State or territory to sub-
 4 mit an application under section 1112, or the fail-
 5 ure, in the determination of the Secretary, of any
 6 State or territory to prepare the application in com-
 7 pliance with such section or to submit the applica-
 8 tion within a reasonable period of time; or

9 “(2) any State or territory informing the Sec-
 10 retary that the State or territory does not intend to
 11 expend the full amount of the grant made to the
 12 State or territory, or the failure of the State or ter-
 13 ritory to expend the full amount allocated to the
 14 State or territory by the end of the fiscal year fol-
 15 lowing the fiscal year for which the allocation was
 16 made;

17 shall be redistributed to the remaining States and terri-
 18 tories in proportion to the original distribution for such
 19 fiscal year to such States and territories.

20 “(d) REQUIREMENT FOR MATCHING FUNDS.—

21 “(1) IN GENERAL.—The Secretary may not
 22 make a grant to a State or territory under section
 23 1110(a) unless the State or territory agrees that,
 24 with respect to the costs to be incurred by the State
 25 or territory in carrying out the program for which

1 the grant was awarded, the State or territory will,
 2 subject to paragraph (2), make available (directly or
 3 through donations from public or private entities)
 4 non-Federal contributions in an amount equal to not
 5 less than \$2 for every \$3 of Federal funds provided
 6 under the grant.

7 “(2) DETERMINATION OF AMOUNT OF NON-
 8 FEDERAL CONTRIBUTION.—Non-Federal contribu-
 9 tions required in paragraph (1) may be in cash or
 10 in kind, fairly evaluated, including plant, equipment,
 11 or services. Amounts provided by the Federal Gov-
 12 ernment, and any portion of any service subsidized
 13 by the Federal Government, may not be included in
 14 determining the amount of such non-Federal con-
 15 tributions.

16 **“SEC. 1114. REGULATIONS, REPORTS, AND AUDITS.**

17 “(a) REGULATIONS.—The Secretary shall promulgate
 18 regulations necessary to carry out this subpart.

19 “(b) REPORTS.—

20 “(1) ANNUAL REPORT BY STATES.—

21 “(A) IN GENERAL.—Not later than 1 year
 22 after the date of enactment of the Genetics and
 23 Public Health Services Act, and annually there-
 24 after, each State and territory shall prepare
 25 and submit to the Administrator of the Health

1 Resources and Services Administration a report
2 that—

3 “(i) describes the purposes for which
4 the State expended payments made to the
5 State under this subpart; and

6 “(ii) contains such additional informa-
7 tion regarding activities authorized in sec-
8 tion 1110, and is submitted in such form,
9 as the Secretary may require.

10 “(B) CRITERIA.—The Administrator of the
11 Health Resources and Services Administration
12 shall develop criteria for the preparation and
13 submission of the annual reports under sub-
14 paragraph (A).

15 “(C) PUBLICATION.—Each State and ter-
16 ritory shall make copies of the report submitted
17 under this paragraph for the fiscal year avail-
18 able for public inspection, and shall upon re-
19 quest provide a copy of the report to any indi-
20 vidual without charge or for a charge not ex-
21 ceeding the cost of providing the copy.

22 “(2) ANNUAL REPORT BY HRSA.—Not later
23 than 1 year after the date of enactment of the Ge-
24 netics and Public Health Services Act, and annually
25 thereafter, the Health Resources and Services Ad-

1 ministration together with the Director for the Cen-
 2 ters for Disease Control and Prevention shall pre-
 3 pare and submit to the Secretary a report that con-
 4 tains a summary of the data contained in the re-
 5 ports submitted with respect to the fiscal year in-
 6 volved under paragraph (1).

7 “(c) FISCAL CONTROLS AND AUDITS.—

8 “(1) IN GENERAL.—Each State and territory
 9 shall establish fiscal control and fund accounting
 10 procedures as may be necessary to assure the proper
 11 disbursal of and accounting for Federal funds paid
 12 to the State under this subpart.

13 “(2) BIENNIAL AUDIT.—Each State and terri-
 14 tory shall biennially audit its expenditures from pay-
 15 ments received under this subpart. Such audits shall
 16 be conducted by an entity independent of any agency
 17 administering a program funded under this subpart
 18 and, in-so-far as practical, in accordance with the
 19 Comptroller General’s standards for auditing govern-
 20 mental organizations, programs, activities, and func-
 21 tions. Within 30 days following the date each audit
 22 is completed, the chief executive officer of the State
 23 shall transmit a copy of that audit to the Secretary.

24 “(3) REPAYMENTS.—Each State and territory
 25 shall, after being provided by the Secretary with

1 adequate notice and opportunity for a hearing within
 2 the State or territory, repay to the United States
 3 amounts found not to have been expended in accord-
 4 ance with the requirements of this subpart. If such
 5 repayment is not made, the Secretary shall, after
 6 providing the State or territory with adequate notice
 7 and opportunity for a hearing within the State or
 8 territory, offset such amounts against the amount of
 9 any payment to which the State or territory is or
 10 may become entitled under this subpart.

11 “(4) PUBLIC INSPECTION.—A State or territory
 12 shall make copies of the audits required by this sub-
 13 section available for public inspection within the
 14 State or territory.

15 **“SEC. 1115. AUTHORIZATION OF APPROPRIATIONS.**

16 “(a) GRANTS AND ADVISORY COMMITTEE ADMINIS-
 17 TRATION.—

18 “(1) IN GENERAL.—There is authorized to be
 19 appropriated for making grants under section
 20 1110(a) and for the administration of the Advisory
 21 Committee under section 1111 \$70,000,000 for each
 22 of fiscal years 2000 through 2009, and such sums
 23 as may be necessary for each succeeding fiscal year.

24 “(2) INCREASE IN AUTHORIZATION.—The
 25 amount described in paragraph (1) for a fiscal year

1 shall be increased from the prior fiscal year based on
2 the increase in the consumer price index for such fis-
3 cal year as determined by the Secretary of Labor.

4 “(3) AVAILABILITY.—Subject to section
5 1113(c), amounts appropriated for a fiscal year
6 under paragraph (1) and unexpended at the end of
7 such fiscal year shall remain available in the suc-
8 ceeding fiscal year.

9 “(4) ADMINISTRATION.—The Secretary shall
10 ensure that, with respect to block grants under sec-
11 tion 1110(a), not more than 20 percent of the
12 amount available for any fiscal year under para-
13 graph (1) will be used for administrative expenses
14 related to such grants.

15 “(b) GRANTS FOR APPLIED PUBLIC HEALTH RE-
16 SEARCH AND SYSTEM DEVELOPMENT.—There is author-
17 ized to be appropriated for making grants for pilot and
18 demonstration projects under section 1110(b)
19 \$30,000,000 for each of fiscal years 2000 through 2009,
20 and such sums as may be necessary for each succeeding
21 fiscal year.

22 “(c) SUPPLEMENTATION.—The Secretary shall en-
23 sure that funds made available under this subpart will
24 supplement and increase the level of funding that would
25 otherwise be made available by the Federal Government

1 for genetic programs and not to supplant such Federal
2 funds.

3 **“SEC. 1116. DEFINITIONS.**

4 “In this subpart:

5 “(1) GENETIC COUNSELING.—The term ‘ge-
6 netic counseling’ means a communication process,
7 the intent of which is to provide individuals and
8 families having a genetic disease or condition or at
9 risk of such a disease or condition, with information
10 about the condition and to provide information that
11 would allow individuals at risk to make informed
12 health care decisions.

13 “(2) STATE.—The term ‘State’ means each of
14 the 50 States and the District of Columbia; and

15 “(2) TERRITORY.—The term “territory” means
16 the Commonwealth of Puerto Rico, the Virgin Is-
17 lands, Guam, American Samoa, the Commonwealth
18 of the Northern Mariana Islands, and the Republic
19 of the Marshall Islands.”.

○