Calendar No. 773

108TH CONGRESS
2D SESSION

S. 518

[Report No. 108–387]

To increase the supply of pancreatic islet cells for research, to provide better coordination of Federal efforts and information on islet cell transplantation, and to collect the data necessary to move islet cell transplantation from an experimental procedure to a standard therapy.

IN THE SENATE OF THE UNITED STATES

MARCH 5, 2003

Ms. COLLINS (for herself, Mrs. MURRAY, Mr. BREAUX, Mr. MILLER, Mr. BUNNING, Mr. LOTT, Mr. DAYTON, Mr. ALLEN, Mr. INHOFE, Mrs. LINCOLN, Mr. DASCHLE, Mr. CHAMBLISS, Mr. SMITH, Mr. DORGAN, Mr. BINGAMAN, Mr. REED, Mr. MCCAIN, Mr. BIDEN, Mr. HARKIN, Mr. CHAFEE, Mr. CRAIG, Mr. HAGEL, Mr. FITZGERALD, Mr. COCHRAN, Mr. DOMENICI, Mr. BOND, Mr. DURBIN, Mr. SESSIONS, Mr. ENSIGN, Mr. ALEXANDER, Mr. WARNER, Mr. KERRY, Mr. GRAHAM of South Carolina, Mr. CORZINE, Mr. DODD, Mrs. CLINTON, Mr. SCHUMER, Mr. NELSON of Nebraska, Ms. MIKULSKI, Mr. LIEBERMAN, Mr. COLEMAN, Mr. FEINGOLD, Mrs. BOXER, Mr. BURNS, Mr. LAUTENBERG, Ms. LANDRIEU, Mr. TALENT, Ms. STABENOW, Mr. DEWINE, Ms. MURKOWSKI, Mr. GRAHAM of Florida, Mr. NELSON of Florida, and Mr. SARBANES) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

OCTOBER 7, 2004

Reported by Mr. GREGG, with an amendment

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

A BILL

To increase the supply of pancreatic islet cells for research,

to provide better coordination of Federal efforts and infomation on islet cell transplantation, and to collect the data necessary to move islet cell transplantation from an experimental procedure to a standard therapy.

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 "Pancreatic Islet Cell Transplantation Act of 2003".~~

~~SEC. 2. FINDINGS.~~

~~Congress makes the following findings:~~

~~(1) Approximately 1,000,000 individuals in the United States have juvenile, or Type I, diabetes.~~

~~(2) In individuals with juvenile diabetes, the body's immune system attacks the pancreas and destroys islet cells that produce insulin.~~

~~(3) Insulin is not a cure and individuals with juvenile diabetes face the constant threat of devastating complications as well as a drastic reduction in their quality of life and shortening of their life span.~~

~~(4) The development of the "Edmonton Protocol" and subsequent variations of that protocol, involving the transplant of insulin-producing pancreatic islet cells into individuals with juvenile diabetes, have brought us within reach of a cure.~~

(5) Islet cell transplants have been hailed as the most promising development in diabetes since the discovery of insulin.

(6) Of the approximately 200 individuals treated using variations of the Edmonton Protocol, nearly 80 percent remain insulin independent after 1 year.

(7) One of the key hurdles in expanding the number of patients enrolled in these protocols is the insufficient number of pancreases available for islet cell transplantation.

(8) Diabetes is the most common cause of kidney failure, accounting for 40 percent of new cases.

(9) While a significant percentage of individuals with Type I diabetes will experience kidney failure and become eligible for benefits under the medicare program, insufficient data exists to conduct an assessment to determine the efficacy of simultaneous islet-kidney transplants or islet transplants after kidney transplants for individuals with Type I diabetes and kidney failure.

(10) The Federal Government should promote policies and regulations to increase the supply of pancreata for research, to coordinate efforts and information in the emerging area of islet cell transplantation, to collect the data necessary to move islet

cell transplantation from an experimental procedure to a standard therapy covered by insurance, and to assess the efficacy of islet transplantation for individuals with Type I diabetes and kidney failure.

SEC. 3. ORGAN PROCUREMENT ORGANIZATION CERTIFICATION.

Section 371 of the Public Health Service Act (42 U.S.C. 273) is amended by adding at the end the following:

''(c) Pancreases procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b).''.

SEC. 4. INTERAGENCY COMMITTEE ON ISLET CELL TRANSPLANTATION.

(a) ESTABLISHMENT.—There is established within the Department of Health and Human Services the Interagency Committee on Islet Cell Transplantation (in this section referred to as the ''Committee'').

(b) MEMBERSHIP.—The Committee shall be composed of a representative from—

(1) the National Institute on Diabetes and Digestive Kidney Diseases, who shall serve as chairperson of the Committee;

(2) the National Institute of Allergy and Infectious Diseases;

(3) the National Institute of Environmental Health Sciences;

(4) the Health Resources and Services Administration;

(5) the Centers for Medicare and Medicaid Services;

(6) the Department of Defense;

(7) the Department of Veterans Affairs;

(8) the National Aeronautics and Space Administration; and

(9) other agencies and National Institutes of Health representatives as determined appropriate by the chairperson and Secretary of Health and Human Services.

(c) DUTIES.—

(1) STUDY.—The Committee shall conduct a study of—

(A) the adequacy of Federal research funding for taking advantage of scientific opportunities relating to islet cell transplantation;

(B) current policies and regulations affecting the supply of pancreases for islet cell transplantation;

(C) the effect of xenotransplantation on advancing islet cell transplantation;

(D) the effect of United Network for Organ Sharing variances on pancreas retrieval and islet cell transplantation; and

(E) the existing mechanisms to collect and coordinate outcome data from existing islet cell transplantation trials.

(2) RECOMMENDATIONS.—The Committee shall develop recommendations concerning the matters studied under paragraph (1).

(3) REPORT.—Not later than 1 year after the date of enactment of this Act and annually thereafter, the Committee shall submit a report to the Secretary of Health and Human Services and the appropriate committees of Congress that shall contain a detailed statement of the findings and conclusions of the Committee, together with recommendations for such legislation and administrative actions as the committee considers appropriate to increase the supply of pancreases available for islet cell transplantation.

SEC. 5. STUDY.

(a) IN GENERAL.—The Secretary of Health and Human Services shall request that the Institute of Medi-

cine conduct, or contract with another entity to conduct, a study on the impact of islet cell transplantation on the health-related quality of life and the economic outcomes for individuals with juvenile diabetes and the cost-effectiveness of such treatment.

(b) MATTERS STUDIED.—The study authorized under this section shall examine and consider the health-related quality of life of juvenile diabetes patients before and after pancreatic cell transplantation. Outcome measures shall include—

(1) clinical outcomes, including episodes of hypoglycemia unawareness and the long-term development of diabetes-related clinical complications, including nephropathy, neuropathy, retinopathy, and vascular disease;

(2) health-related quality of life outcomes, including patient levels of worry with respect to fear of hypoglycemia episodes, the ability to perform basic life and work-associated functions, and the impact on the quality of life of family members and caregivers; and

(3) the cost-effectiveness of pancreatic islet cell transplantation, as compared to both standard medical management (such as continued daily insulin in-

jections) and whole pancreas transplantation, for patients with juvenile diabetes.

(c) COST-EFFECTIVENESS ANALYSIS.—Cost-effectiveness analysis, as described in subsection (b)(3), shall include standard health profile instruments to assess post-treatment costs and benefits, including—

(1) direct measures, such as—

(A) post-transplant health care resource utilization; and

(B) long-term health care resource utilization due to diabetes complications, including nephropathy, neuropathy, retinopathy, and vascular disease which can extend to include sight loss and limb loss; and

(2) indirect measures, such as—

(A) time lost at work; and

(B) productivity analysis.

SEC. 6. MEDICARE DEMONSTRATION PROJECT.

(a) ESTABLISHMENT OF PROJECT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services and in consultation with the Director of the National Institutes of Health and the Administrator of the Agency for Healthcare Research and Quality (in this

section referred to as the ''Secretary'') shall establish a demonstration project (in this section referred to as the ''project'') to assess the efficacy of pancreatic islet cell transplantation for individuals with Type I diabetes, who are medically determined to have end-stage renal disease, and who are beneficiaries under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(2) ASSESSMENT OF ISLET TRANSPLANTS.—The project shall assess the efficacy of simultaneous islet-kidney transplants as well as islet transplants after a kidney transplant for individuals with Type I diabetes and kidney failure.

(b) DURATION.—The Secretary shall conduct the demonstration project under this section for a 5-year period.

(c) SELECTION OF PARTICIPATING FACILITIES.—

(1) COMPETITIVE SELECTION.—Subject to paragraph (2), the Secretary shall select eligible facilities to participate in the project on a competitive basis.

(2) LIMITATION.—No more than 6 eligible facilities may participate in the project.

(3) ELIGIBLE FACILITY DEFINED.—In this section, the term eligible facility means a facility that—

(A) is eligible to receive payments under section 1881 of the Social Security Act (42 U.S.C. 1395rr);

(B) has experience performing islet cell transplants; and

(C) agrees to provide such data to the Secretary as the Secretary determines is necessary to conduct the evaluation under subsection (d)(1).

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall conduct an evaluation of the outcomes under the project to assess the efficacy of pancreatic islet cell transplantation for individuals with Type I diabetes who are medically determined to have end-stage renal disease.

(2) REPORT.—Not later than 120 days after the date on which the project is completed, the Secretary shall submit to Congress a report on the evaluation conducted under paragraph (1) together with such recommendations for legislative and administrative actions that the Secretary determines are appropriate.

~~(c) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq. and 1395 et seq.) as may be necessary for the purposes of carrying out the project.~~

~~SEC. 7. AUTHORIZATION OF APPROPRIATIONS.~~

~~There are authorized to be appropriated such sums as may be necessary to carry out this Act.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pancreatic Islet Cell Transplantation Act of 2004".

SEC. 2. ORGAN PROCUREMENT ORGANIZATION CERTIFICATION.

Section 371 of the Public Health Service Act (42 U.S.C. 273) is amended by adding at the end the following:

"(c) Pancreases procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b).".

SEC. 3. ANNUAL ASSESSMENT ON PANCREATIC ISLET CELL TRANSPLANTATION.

Section 429 of the Public Health Service Act (42 U.S.C. 285c–3) is amended by adding at the end the following:

"(d) In each annual report prepared by the Diabetes Mellitus Interagency Coordinating Committee pursuant to subsection (c), the Committee shall include an assessment of the Federal activities and programs related to pancreatic islet cell transplantation. Such assessment shall, at a minimum, address the following:

"(1) The adequacy of Federal funding for taking advantage of scientific opportunities relating to pancreatic islet cell transplantation.

"(2) Current policies and regulations affecting the supply of pancreata for islet cell transplantation.

"(3) The effect of xenotransplantation on advancing pancreatic islet cell transplantation.

"(4) The effect of United Network for Organ Sharing policies regarding pancreas retrieval and islet cell transplantation.

"(5) The existing mechanisms to collect and coordinate outcomes data from existing islet cell transplantation trials.

"(6) Implementation of multiagency clinical investigations of pancreatic islet cell transplantation.

"(7) Recommendations for such legislation and administrative actions as the Committee considers appropriate to increase the supply of pancreases available for islet cell transplantation.".

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