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108TH CONGRESS
1ST SESSION

H. R. 1068

To increase the supply of pancreatic islet cells for research, to provide better coordination of Federal efforts and information on islet cell transplantation, to collect the data necessary to move islet cell transplantation from an experimental procedure to a standard therapy, and to provide for a demonstration project on Medicare coverage of pancreatic islet cell transplantation for beneficiaries with type 1 diabetes who have end-stage renal disease.

IN THE HOUSE OF REPRESENTATIVES

MARCH 4, 2003

Mr. NETHERCUTT (for himself, Ms. DEGETTE, Mr. BECERRA, Mr. WELDON of Pennsylvania, Mr. RANGEL, Ms. HART, and Mr. CUNNINGHAM) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To increase the supply of pancreatic islet cells for research, to provide better coordination of Federal efforts and information on islet cell transplantation, to collect the data necessary to move islet cell transplantation from an experimental procedure to a standard therapy, and to provide for a demonstration project on Medicare coverage of pancreatic islet cell transplantation for beneficiaries with type 1 diabetes who have end-stage renal disease.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Pancreatic Islet Cell Transplantation Act of 2003''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

The Congress makes the following findings:

(1) Approximately 1,000,000 individuals in the United States have juvenile, or Type 1, 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, a drastic reduction in quality of life, and a shortened life span.

(4) The development of the ''Edmonton Protocol'' and subsequent variations of that protocol, involving the transplant of insulin-producing pan-

creatic 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) Currently 80 percent of the approximately 200 patients who have received islet cell transplants using variations of the Edmonton Protocol have maintained normal glucose levels without insulin injections 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) While a significant percentage of individuals with type 1 diabetes will experience kidney failure and become Medicare-eligible through the end stage renal disease program, insufficient data exist to conduct an assessment to determine the efficacy of simultaneous islet-kidney transplants and islet transplants after kidney transplants for individuals with type 1 diabetes.

(9) The Federal Government should promote policies and regulations to increase the supply of pancreases for research, to coordinate efforts and in-

formation 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 create a medicare demonstration project to determine the efficacy of simultaneous islet-kidney transplants and islet transplants after kidney transplants for medicare beneficiaries with type 1 diabetes.

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 the following:

(1) 1 member appointed by the Director of the National Institute on Diabetes and Digestive Kidney Diseases, which member shall serve as chairperson of the Committee.

(2) 1 member appointed by the Director of the National Institute of Allergy and Infectious Diseases.

(3) 1 member appointed by the Director of the National Institute of Environmental Health Sciences.

(4) 1 member appointed by the Administrator of the Health Resources and Services Administration.

(5) 1 member appointed by the Administrator of the Centers for Medicare and Medicaid Services.

(6) 1 member appointed by the Secretary of Defense.

(7) 1 member appointed by the Secretary of Veterans Affairs.

(8) 1 member appointed by the Administrator of the National Aeronautics and Space Administration.

(9) Such members as the Secretary of Health and Human Services, in consultation with the chairperson of the Committee, determines appropriate

and appoints to represent agencies (including the national research institutes of the National Institutes of Health) that are not listed in paragraphs (1) through (8).

(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 the Congress containing 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 OF ISLET CELL TRANSPLANTATION.

(a) IN GENERAL.—The Secretary of Health and Human Services shall request that the Institute of Medicine 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 injections) 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 PANCREATIC ISLET CELL TRANSPLANT DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—In order to test the efficacy of pancreatic islet cell transplantation, not later than 120 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish a demonstration project which provides over a 5-year period for payment under the medicare program under title XVIII of the Social Security Act for pancreatic islet cell transplantation in the case of medicare beneficiaries who have type 1 (juvenile) diabetes and have end stage renal disease.

(b) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the outcomes of the demonstration project. Not later than 120 days after the date of completion of the demonstration project, the Secretary shall submit to Congress a report on the project, including recommendations for such legislative and administrative action as the Secretary deems appropriate.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

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

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