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THE PANCREATIC ISLET CELL TRANSPLANTATION ACT OF 2004

OCTOBER 7, 2004.—Ordered to be printed

Mr. GREGG, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

[To accompany S. 518]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 518) 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, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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I. PURPOSE AND NEED FOR LEGISLATION

Diabetes is a lifelong disease that affects people of every age, race, and nationality. According to the National Diabetes Information Clearinghouse, a service of the National Institute of Diabetes, Digestive and Kidney Diseases, 17 million Americans—6.2 percent of the population—suffer from diabetes, and about 800,000 new cases are diagnosed each year. Type 1 diabetes, frequently referred to as juvenile diabetes, usually starts early in life and renders individuals insulin-dependent for life. Currently, there is no method to prevent or cure Type 1 diabetes, and available treatments, including insulin injections, have only limited success in controlling its consequences.

Pancreatic islet cell transplantation is an important advance in diabetes treatment. Once implanted, the new islet cells release insulin into the patient's bloodstream in response to glucose. This new procedure has helped up to 80% of patients become insulin-independent up to one year post-transplantation.

However, a shortage of donor pancreata is a barrier to higher transplant rates. In 2001, approximately 1,800 pancreata were donated and only 500 were available for islet cell transplantation and research. At the same time, more than one million people suffer from juvenile diabetes.

Current Federal regulations do not credit organ procurement organizations (OPOs) for harvesting pancreases for islet cell transplantation toward their certification or recertification.

II. SUMMARY

S. 518 amends the Public Health Service Act to include pancreases procured for islet cell transplantation for certification purposes of organ procurement organizations.

The legislation also requires the Diabetes Mellitus Interagency Coordinating Committee to annually assess Federal activities and programs related to pancreatic islet cell transplantation.

III. HISTORY OF LEGISLATION AND VOTES IN COMMITTEE

On March 5, 2003, Senator Collins (for herself) and Senators Murray, Breaux and Miller introduced S. 518, Pancreatic Islet Cell Transplantation Act of 2003. On March 2, 2004, Senator Collins (for herself) and Senators Murray, Warner, Bingaman, Allen, Feingold, Cochran, Lautenberg, Hagel, Reed, Smith, Ensign and DeWine introduced S. 2158, Pancreatic Islet Cell Transplantation of 2004.

On September 20, 2004, Senator Gregg offered a substitute amendment to S. 518 with previously agreed language from S. 2158. S. 518, as amended, was approved by the committee by unanimous consent.

Previously, Section 6 of S. 518 was incorporated into the Medicare Modernization Act. It created a Medicare Demonstration 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 are Medicare beneficiaries.

IV. EXPLANATION OF BILL AND COMMITTEE VIEWS

This legislation is intended to assist and encourage those parties interested in the successful development of islet cell research and transplantation to participate actively in the national discourse on this important subject. The provisions contained in the legislation are not intended to alter the authority of the OPTN as the policy making body for solid organ allocation.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 7, 2004.

Hon. JUDD GREGG,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 518, the Pancreatic Islet Cell Transplantation Act of 2004.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Christopher J. Topoleski.

Sincerely,

DOUGLAS HOLTZ-EAKIN, *Director.*

Enclosure.

S. 518.—Pancreatic Islet Cell Transplantation Act of 2004

S. 518 would require that organizations that procure pancreases for islet cell transplant or research be subject to the certification and recertification process that applies to other organ procurement organizations under section 371 of the Public Health Service Act.

In addition, the bill would require the Diabetes Mellitus Interagency Coordinating Committee, which currently exists, to include in its annual report an assessment of federal involvement related to pancreatic islet cell transplantation. That assessment would include a discussion of adequacy in funding; current policies, regulations, and procedures related to pancreas procurement and cell transplant; policies of the United Network for Organ Sharing regarding pancreas retrieval and cell transplant; existing data collection methods; clinical investigations related to pancreatic islet cell transplantation; and any legislative or administrative recommendations that the committee may have.

CBO estimates that implementing S. 518 would cost less than $500,000 in each year over the 2005–2009 period, assuming the availability of appropriated funds. Enacting S. 518 would not affect direct spending or revenues.

S. 518 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

On October 4, 2004, CBO transmitted identical cost estimates for H.R. 3858, the Pancreatic Islet Cell Transplantation Act of 2004, as ordered reported by the House Committee on Energy and Commerce on September 30, 2004, and S. 2158, the Pancreatic Islet Cell Transplantation Act of 2004. The Committee on Health, Edu-

cation, Labor, and Pensions approved the text of S. 2158 as an amendment in the nature of a substitute for S. 518.

The CBO staff contact for this estimate is Christopher J. Topoleski. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VI. REGULATORY IMPACT STATEMENT

The committee has determined that there will be de minimus changes in the regulatory burden imposed by the bill.

VII. APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1, the Congressional Accountability Act (CAA) requires a description of the application of this bill to the legislative branch. This bill does not amend any act that applies to the legislative branch.

VIII. SECTION-BY-SECTION ANALYSIS

Section 1. Short title

Section 1 names the legislation the Pancreatic Islet Cell Transplantation Act of 2004.

Section 2. Organ procurement organization certification

Section 2 amends Section 371 of the Public Health Service Act (42 U.S.C. 273) and directs the Center for Medicare and Medicaid Services (CMS) to grant "credit" to organ procurement organizations (OPOs)—towards certification and recertification—for pancreases procured and used for islet cell transplantation or research.

Section 3. Annual assessment on pancreatic islet cell transplantation

Section 3 amends Section 429 of the Public Health Service Act (42 U.S.C. 285c–3) to require the Diabetes Mellitus Interagency Coordinating Committee (DIMCC) to conduct an annual assessment of federal efforts related to islet transplantation. The legislation requires the DIMCC to evaluate Federal research funding for islet transplantation, the effect of specific policies on transplantation, data collection, and federal coordination, and make recommendations to the Secretary of HHS.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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PART H—ORGAN TRANSPLANTS

ORGAN PROCUREMENT ORGANIZATIONS

SEC. 371. (a)(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).

(Z) * * *

* * * * * * *

(b)(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—

(A) * * *

* * * * * * *

(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).

* * * * * * *

INTERAGENCY COORDINATING COMMITTEES

SEC. 429. (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

(2) * * *

* * * * * * *

(c) Each Committee shall prepare an annual report for—

(1) the Secretary;

(2) * * *

* * * * * * *

(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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