

PANCREATIC ISLET CELL TRANSPLANTATION ACT OF  
2004

OCTOBER 5, 2004.—Committed to the Committee of the Whole House on the State  
of the Union and ordered to be printed

Mr. BARTON of Texas, from the Committee on Energy and  
Commerce, submitted the following

R E P O R T

[To accompany H.R. 3858]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3858) to amend the Public Health Service Act to increase the supply of pancreatic islet cells for research, and to provide for better coordination of Federal efforts and information on islet cell transplantation, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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#### PURPOSE AND SUMMARY

The purpose of H.R. 3858 is to increase the supply of pancreatic islet cells for research by requiring pancreata procured by an organ procurement organization and used for islet cell transplantation or research to be counted for purposes of certification or recertification.

#### BACKGROUND AND NEED FOR LEGISLATION

Through an experimental procedure commonly referred to as islet cell transplantation, islet cells are removed from a donor pancreas and transferred into another person. Once implanted, the beta cells in these islets begin to make and release insulin. Researchers hope that islet cell transplantation will help people with type 1 diabetes live without daily injections of insulin.

Section 371 of the Public Health Service Act outlines federal grant programs and certification requirements for organ procurement organizations, including a provision authorizing organ procurement organizations to carry out special projects designed to increase the number of organ donors. By permitting pancreata donated for the purposes of islet cell transplantation or research to be counted for purposes of certification or recertification, the Committee expects the number of pancreatic and other organ donations to increase, expanding the capabilities of pancreatic islet cell research.

#### HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

#### COMMITTEE CONSIDERATION

On Thursday, September 30, 2004, the Full Committee met in open markup session and ordered H.R. 3858 favorably reported to the House, without amendment, by a voice vote, a quorum being present.

#### COMMITTEE VOTES

There were no record votes taken in connection with ordering H.R. 3858 reported. A motion by Mr. Barton to order H.R. 3858 reported to the House, without amendment, was agreed to by a voice vote.

#### COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

#### STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

To increase the supply of pancreatic islet cells for research by requiring pancreata procured by an organ procurement organization and used for islet cell transplantation or research to be counted for purposes of certification or recertification.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX  
EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 3858, the Pancreatic Islet Cell Transplantation Act of 2004, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, October 4, 2004.*

Hon. JOE BARTON,  
*Chairman, Committee on Energy and Commerce,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3858, 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.

*H.R. 3858—Pancreatic Islet Cell Transplantation Act of 2004*

H.R. 3858 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 H.R. 3858 would cost less than \$500,000 in each year over the 2005–2009 period, assuming the availability of appropriated funds. Enacting H.R. 3858 would not affect direct spending or revenues.

H.R. 3858 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 a cost estimate for S. 2158, the Pancreatic Islet Cell Transplantation Act of 2004, as ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on September 23, 2004. The two bills are identical, as are CBO's two cost estimates.

The CBO staff contact for this estimate is Christopher J. Topoleski, who can be reached at 226–9010. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

#### FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

#### ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

#### CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

#### APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

#### SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

##### *Section 1. Short title*

This section provides the short title of the bill, 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 to require that pancreata procured by an organ procurement organization and used for islet cell transplantation or research be counted for purposes of certification or recertification of organ procurement centers.

*Section 3. Annual assessment on pancreatic islet cell transplantation*

Section 3 requires the Diabetes Mellitus Interagency Coordinating Committee, as authorized by section 429 of the Public Health Service Act, to complete an annual report assessing Federal activities and programs relating to pancreatic islet cell transplantation, including an evaluation of the adequacy of funding levels, current policies and regulations affecting the supply of islet cells, the effect of xenotransplantation on advancing pancreatic islet cell transplantation, the effect of United Network for Organ Sharing policies regarding pancreatic retrieval and islet cell transplantations, data collection activities, implementation of multiagency clinical investigations of islet cell transplantation, and recommendations for legislative and administrative changes to increase the supply of pancreatic islet cells.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

**PUBLIC HEALTH SERVICE ACT**

\* \* \* \* \*

**TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE**

\* \* \* \* \*

**PART H—ORGAN TRANSPLANTS**

\* \* \* \* \*

**Subpart 3—Mammography Facilities**

\* \* \* \* \*

**ORGAN PROCUREMENT ORGANIZATIONS**

SEC. 371. (a) \* \* \*

\* \* \* \* \*

*(c) Pancreata 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).*

\* \* \* \* \*

**TITLE IV—NATIONAL RESEARCH INSTITUTES**

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**PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES**

\* \* \* \* \*

Subpart 3—National Institute of Diabetes and Digestive and  
Kidney Diseases

\* \* \* \* \*

INTERAGENCY COORDINATING COMMITTEES

SEC. 429. (a) \* \* \*

\* \* \* \* \*

*(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 pancreata available for islet cell transplantation.*

\* \* \* \* \*