

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

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.

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; TABLE OF CONTENTS.**

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

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

Sec. 1. Short title.

Sec. 2. Findings.

Sec. 3. Organ procurement organization certification.

Sec. 4. Interagency Committee on Islet Cell Transplantation.

Sec. 5. Study of islet cell transplantation.

Sec. 6. Medicare pancreatic islet cell transplant demonstration project.

Sec. 7. Authorization of appropriations.

8 **SEC. 2. FINDINGS.**

9 The Congress makes the following findings:

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

12 (2) In individuals with juvenile diabetes, the
13 body’s immune system attacks the pancreas and de-
14 stroys islet cells that produce insulin.

15 (3) Insulin is not a cure, and individuals with
16 juvenile diabetes face the constant threat of dev-
17 astating complications, a drastic reduction in quality
18 of life, and a shortened life span.

19 (4) The development of the “Edmonton Pro-
20 tocol” and subsequent variations of that protocol, in-
21 volving the transplant of insulin-producing pan-

1 creatic islet cells into individuals with juvenile diabe-
2 tes, have brought us within reach of a cure.

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

6 (6) Currently 80 percent of the approximately
7 200 patients who have received islet cell transplants
8 using variations of the Edmonton Protocol have
9 maintained normal glucose levels without insulin in-
10 jectons after 1 year.

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

15 (8) While a significant percentage of individuals
16 with type 1 diabetes will experience kidney failure
17 and become Medicare-eligible through the end stage
18 renal disease program, insufficient data exist to con-
19 duct an assessment to determine the efficacy of si-
20 multaneous islet-kidney transplants and islet trans-
21 plants after kidney transplants for individuals with
22 type 1 diabetes.

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

1 formation in the emerging area of islet cell trans-
2 plantation, to collect the data necessary to move islet
3 cell transplantation from an experimental procedure
4 to a standard therapy covered by insurance, and to
5 create a medicare demonstration project to deter-
6 mine the efficacy of simultaneous islet-kidney trans-
7 plants and islet transplants after kidney transplants
8 for medicare beneficiaries with type 1 diabetes.

9 **SEC. 3. ORGAN PROCUREMENT ORGANIZATION CERTIFI-**
10 **CATION.**

11 Section 371 of the Public Health Service Act (42
12 U.S.C. 273) is amended by adding at the end the fol-
13 lowing:

14 “(c) Pancreases procured by an organ procurement
15 organization and used for islet cell transplantation or re-
16 search shall be counted for purposes of certification or re-
17 certification under subsection (b).”.

18 **SEC. 4. INTERAGENCY COMMITTEE ON ISLET CELL TRANS-**
19 **PLANTATION.**

20 (a) ESTABLISHMENT.—There is established within
21 the Department of Health and Human Services the Inter-
22 agency Committee on Islet Cell Transplantation (in this
23 section referred to as the “Committee”).

24 (b) MEMBERSHIP.—The Committee shall be com-
25 posed of the following:

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

5 (2) 1 member appointed by the Director of the
6 National Institute of Allergy and Infectious Dis-
7 eases.

8 (3) 1 member appointed by the Director of the
9 National Institute of Environmental Health
10 Sciences.

11 (4) 1 member appointed by the Administrator
12 of the Health Resources and Services Administra-
13 tion.

14 (5) 1 member appointed by the Administrator
15 of the Centers for Medicare and Medicaid Services.

16 (6) 1 member appointed by the Secretary of
17 Defense.

18 (7) 1 member appointed by the Secretary of
19 Veterans Affairs.

20 (8) 1 member appointed by the Administrator
21 of the National Aeronautics and Space Administra-
22 tion.

23 (9) Such members as the Secretary of Health
24 and Human Services, in consultation with the chair-
25 person of the Committee, determines appropriate

1 and appoints to represent agencies (including the
2 national research institutes of the National Insti-
3 tutes of Health) that are not listed in paragraphs
4 (1) through (8).

5 (c) DUTIES.—

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

8 (A) the adequacy of Federal research fund-
9 ing for taking advantage of scientific opportuni-
10 ties relating to islet cell transplantation;

11 (B) current policies and regulations affect-
12 ing the supply of pancreases for islet cell trans-
13 plantation;

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

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

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

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

1 (3) REPORT.—Not later than 1 year after the
2 date of enactment of this Act and annually there-
3 after, the Committee shall submit a report to the
4 Secretary of Health and Human Services and the
5 appropriate committees of the Congress containing a
6 detailed statement of the findings and conclusions of
7 the Committee, together with recommendations for
8 such legislation and administrative actions as the
9 committee considers appropriate to increase the sup-
10 ply of pancreases available for islet cell transplan-
11 tation.

12 **SEC. 5. STUDY OF ISLET CELL TRANSPLANTATION.**

13 (a) IN GENERAL.—The Secretary of Health and
14 Human Services shall request that the Institute of Medi-
15 cine conduct, or contract with another entity to conduct,
16 a study on the impact of islet cell transplantation on the
17 health-related quality of life and the economic outcomes
18 for individuals with juvenile diabetes, and the cost-effec-
19 tiveness of such treatment.

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

1 (1) clinical outcomes, including episodes of
2 hypoglycemia unawareness and the long-term devel-
3 opment of diabetes-related clinical complications, in-
4 cluding nephropathy, neuropathy, retinopathy, and
5 vascular disease;

6 (2) health-related quality of life outcomes, in-
7 cluding patient levels of worry with respect to fear
8 of hypoglycemia episodes, the ability to perform
9 basic life and work-associated functions, and the im-
10 pact on the quality of life of family members and
11 caregivers; and

12 (3) the cost-effectiveness of pancreatic islet cell
13 transplantation, as compared to both standard med-
14 ical management (such as continued daily insulin in-
15 jections) and whole pancreas transplantation, for pa-
16 tients with juvenile diabetes.

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

21 (1) direct measures, such as—

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

24 (B) long-term health care resource utiliza-
25 tion due to diabetes complications, including

1 nephropathy, neuropathy, retinopathy, and vas-
2 cular disease which can extend to include sight
3 loss and limb loss; and

4 (2) indirect measures, such as—

5 (A) time lost at work; and

6 (B) productivity analysis.

7 **SEC. 6. MEDICARE PANCREATIC ISLET CELL TRANSPLANT**
8 **DEMONSTRATION PROJECT.**

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

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

1 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

2 There are authorized to be appropriated such sums

3 as may be necessary to carry out this Act.

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