

107TH CONGRESS
2^D SESSION

H. R. 5462

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 HOUSE OF REPRESENTATIVES

SEPTEMBER 25, 2002

Mr. NETHERCUTT (for himself, Ms. DEGETTE, Mr. WELDON of Pennsylvania, and Mr. LAFALCE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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, and to collect the data necessary to move islet cell transplantation from an experimental procedure to a standard therapy.

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.**

4 This Act may be cited as the “Pancreatic Islet Cell
5 Transplantation Act of 2002”.

6 **SEC. 2. FINDINGS.**

7 The Congress makes the following findings:

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

3 (2) In individuals with juvenile diabetes, the
4 body's immune system attacks the pancreas and de-
5 stroys islet cells that produce insulin.

6 (3) Insulin is not a cure, and individuals with
7 juvenile diabetes face the constant threat of dev-
8 astating complications, a drastic reduction in quality
9 of life, and a shortened life span.

10 (4) The development of the "Edmonton Pro-
11 tocol" and subsequent variations of that protocol, in-
12 volving the transplant of insulin-producing pan-
13 creatic islet cells into individuals with juvenile diabe-
14 tes, have brought us within reach of a cure.

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

18 (6) Currently 80 percent of the approximately
19 70 patients who have received islet cell transplants
20 using variations of the Edmonton Protocol have
21 maintained normal glucose levels without insulin in-
22 jections after 1 year.

23 (7) One of the key hurdles in expanding the
24 number of patients enrolled in these protocols is the

1 insufficient number of pancreases available for islet
2 cell transplantation.

3 (8) The Federal Government should promote
4 policies and regulations to increase the supply of
5 pancreases for research, to coordinate efforts and in-
6 formation in the emerging area of islet cell trans-
7 plantation, and to collect the data necessary to move
8 islet cell transplantation from an experimental proce-
9 dure to a standard therapy covered by insurance.

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

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

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

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

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

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

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

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

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

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

16 (5) 1 member appointed by the Administrator
17 of the Centers for Medicare and Medicaid Services.

18 (6) 1 member appointed by the Secretary of
19 Defense.

20 (7) 1 member appointed by the Secretary of
21 Veterans Affairs.

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

1 (9) Such members as the Secretary of Health
2 and Human Services, in consultation with the chair-
3 person of the Committee, determines appropriate
4 and appoints to represent agencies (including the
5 national research institutes of the National Insti-
6 tutes of Health) that are not listed in paragraphs
7 (1) through (8).

8 (c) DUTIES.—

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

11 (A) the adequacy of Federal research fund-
12 ing for taking advantage of scientific opportuni-
13 ties relating to islet cell transplantation;

14 (B) current policies and regulations affect-
15 ing the supply of pancreases for islet cell trans-
16 plantation;

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

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

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

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

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

15 **SEC. 5. STUDY.**

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

23 (b) MATTERS STUDIED.—The study authorized
24 under this section shall examine and consider the health-
25 related quality of life of juvenile diabetes patients before

1 and after pancreatic cell transplantation. Outcome meas-
2 ures shall include—

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

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

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

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

23 (1) direct measures, such as—

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

1 (B) long-term health care resource utiliza-
2 tion due to diabetes complications, including
3 nephropathy, neuropathy, retinopathy, and vas-
4 cular disease which can extend to include sight
5 loss and limb loss; and

6 (2) indirect measures, such as—

7 (A) time lost at work; and

8 (B) productivity analysis.

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