

107TH CONGRESS
2^D SESSION

S. 2849

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 SENATE OF THE UNITED STATES

AUGUST 1, 2002

Ms. COLLINS (for herself and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 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 as well as a drastic reduction
9 in their quality of life and shortening of their life
10 span.

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

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

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

24 (7) One of the key hurdles in expanding the
25 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 a representative from—

3 (1) the National Institute on Diabetes and Di-
4 gestive Kidney Diseases, who shall serve as chair-
5 person of the Committee;

6 (2) the National Institute of Allergy and Infec-
7 tious Diseases;

8 (3) the National Institute of Environmental
9 Health Sciences;

10 (4) the Health Resources and Services Adminis-
11 tration;

12 (5) the Centers for Medicare and Medicaid
13 Services;

14 (6) the Department of Defense;

15 (7) the Department of Veterans Affairs;

16 (8) the National Aeronautics and Space Admin-
17 istration; and

18 (9) other agencies and National Institutes of
19 Health representatives as determined appropriate by
20 the chairperson and Secretary of Health and Human
21 Services.

22 (c) DUTIES.—

23 (1) STUDY.—The Committee shall conduct a
24 study of—

1 (A) the adequacy of Federal research fund-
2 ing for taking advantage of scientific opportuni-
3 ties relating to islet cell transplantation;

4 (B) current policies and regulations affect-
5 ing the supply of pancreases for islet cell trans-
6 plantation;

7 (C) the effect of xenotransplantation on
8 advancing islet cell transplantation;

9 (D) the effect of United Network for
10 Organ Sharing variances on pancreas retrieval
11 and islet cell transplantation; and

12 (E) the existing mechanisms to collect and
13 coordinate outcome data from existing islet cell
14 transplantation trials.

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

18 (3) REPORT.—Not later than 1 year after the
19 date of enactment of this Act and annually there-
20 after, the Committee shall submit a report to the
21 Secretary of Health and Human Services and the
22 appropriate committees of Congress that shall con-
23 tain a detailed statement of the findings and conclu-
24 sions of the Committee, together with recommenda-
25 tions for such legislation and administrative actions

1 as the committee considers appropriate to increase
2 the supply of pancreases available for islet cell trans-
3 plantation.

4 **SEC. 5. STUDY.**

5 (a) IN GENERAL.—The Secretary of Health and
6 Human Services shall request that the Institute of Medi-
7 cine conduct, or contract with another entity to conduct,
8 a study on the impact of islet cell transplantation on the
9 health-related quality of life and the economic outcomes
10 for individuals with juvenile diabetes and the cost-effec-
11 tiveness of such treatment.

12 (b) MATTERS STUDIED.—The study authorized
13 under this section shall examine and consider the health-
14 related quality of life of juvenile diabetes patients before
15 and after pancreatic cell transplantation. Outcome meas-
16 ures shall include—

17 (1) clinical outcomes, including episodes of
18 hypoglycemia unawareness and the long-term devel-
19 opment of diabetes-related clinical complications, in-
20 cluding nephropathy, neuropathy, retinopathy, and
21 vascular disease;

22 (2) health-related quality of life outcomes, in-
23 cluding patient levels of worry with respect to fear
24 of hypoglycemia episodes, the ability to perform
25 basic life and work-associated functions, and the im-

1 pact on the quality of life of family members and
2 caregivers; and

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

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

12 (1) direct measures, such as—

13 (A) post-transplant health care resource
14 utilization; and

15 (B) long-term health care resource utiliza-
16 tion due to diabetes complications, including
17 nephropathy, neuropathy, retinopathy, and vas-
18 cular disease which can extend to include sight
19 loss and limb loss; and

20 (2) indirect measures, such as—

21 (A) time lost at work; and

22 (B) productivity analysis.

1 **SEC. 6. AUTHORIZATION OF APPROPRIATIONS.**

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

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