Legislative Fiscal Bureau
One East Main, Suite 301 • Madison, WI 53703 • (608) 266-3847 • Fax: (608) 267-6873

June 5, 2007 Joint Committee on Finance Paper #824

Islet Transplantation (UW System)

Bill Agency

[LFB 2007-09 Budget Summary: Page 573, #9]

CURRENT LAW

No provision.

GOVERNOR

Provide $200,000 GPR annually to support research related to islet transplantation at the UW School of Medicine and Public Health (Medical School).

DISCUSSION POINTS

1. Islet transplantation is an experimental treatment for type 1 (juvenile) diabetes. Islets are cell clusters in the pancreas that release the amount of insulin necessary to maintain normal sugar levels in the body. The destruction of these cells is the cause of type 1 diabetes. Islet cell transplantation infuses new islet cells into a patient's liver, where they produce insulin as needed. If the islet transplantation is successful, the patient would no longer have to use insulin injection treatments as his or her body would make the necessary insulin.

2. The UW Medical School began its islet transplantation program in 2002. Following successful clinical trials related to islet transplantations at other institutions, a pilot clinical trial at the UW Medical School was approved by the Institutional Review Board (IRB) and the Food and Drug Administration (FDA). A collaborative agreement was then established with Washington University in St. Louis such that that university would provide the UW Medical School with

processed islet cells for use in the clinical trial. Three patients received transplants as part of this initial trial.

3. During the course of this first pilot clinical trial, the UW Medical School established an islet isolation facility at the Waisman Clinical Biomanufacturing Facility (WCBF) to accommodate a planned expansion of the clinical program. Using this facility, the islet transplantation program can produce islet cells that are suitable for clinical use and that meet guidelines set by the Food and Drug Administration (FDA). This facility has been operational since 2004.

4. Since then, an additional six patients with type 1 diabetes have received infusions containing islets processed at the UW Medical School facility located in WCBF. Of the nine total patients who have received transplants, four are currently insulin independent and four have experienced a significant reduction in the number of insulin injections required and show increased glycemic control. It is too early to know whether the transplant to the ninth patient, who recently received her first transfusion, has been successful.

5. In addition, the UW Medical School has recently been named an Islet Cell Resource Center (ICR). As such, the University will receive funding from the National Institute for Health (NIH) to provide eligible FDA-approved investigators and scientists with pancreatic islets for clinical and research use. There are currently 10 other ICRs located throughout the country.

6. The requested funding would support the islet transplantation program at the UW Medical School. Most of the funding would support costs associated with the islet processing facility at WCBF. According to the UW System, costs related to this space range from between $132,000 and $147,000. Most of the variation in cost is due to estimates related to labor costs. WCBF is the only facility located on the UW-Madison campus that has space which meets the current Good Manufacturing Product Standards (cGMP), required by the FDA for clinical trials.

7. The cost of a complete islet transplantation is roughly $200,000 per patient. As this treatment is in the clinical trial phase, these costs would not be reimbursed by a patient's health insurance and cannot be funded through NIH research grants. The funding provided in SB 40 would defray the cost of these procedures to patients. In addition, these funds may be used to leverage grant funds from sources that require state matching funds.

8. Currently, islet transplants are funded through allocations from the University's base funding, private gifts and grants, and contributions made by the individual patients. If the funding provided in SB 40 would be deleted, this research could continue to be funded through the existing funding sources.

ALTERNATIVES TO BILL

1. Approve the Governor's recommendation.

ALT 1	Change to Bill Funding	Change to Base Funding
GPR	$0	$400,000

2. Delete provision.

ALT 2	Change to Bill Funding	Change to Base Funding
GPR	- $400,000	$0

Prepared by: Emily Pope