INTRODUCTION

A Special Statutory Funding Program for Type 1 Diabetes
Research is mandated by Section 330B of the Public Health
Service Act. This program was initially established by Section
4921 of the Balanced Budget Act of 1997 (P.L. 105-33)
and later extended and augmented by Section 931 of the 2001
Consolidated Appropriations Act (P.L. 106-554) and by the Public
Health Service Act Amendment for Diabetes (P.L. 107-360).
Section 330B states:

Sec. 330B. [254c-2] Special Diabetes Programs for Type 1 Diabetes

"(a) In General. – The Secretary, directly or through grants, shall provide for research into the prevention and cure of Type 1 diabetes."

"(b) Funding.-

- (1) Transferred Funds. Notwithstanding section 2140(a) of the Social Security Act, from the amounts appropriated in such section for each of the fiscal years 1998 through 2002, \$30,000,000 is hereby transferred and made available in such fiscal years for grants under this section."
- "(2) Appropriations. For the purpose of making grants under this section, there is appropriated, out of any funds in the Treasury not otherwise appropriated
 - (A) \$70,000,000 for each of fiscal years 2001 and 2002 (which shall be combined with amounts transferred under paragraph (1) for each such fiscal years);
 - (B) \$100,000,000 for fiscal year 2003; and
 - (C) \$150,000,000 for fiscal years 2004 through 2008."

This program also has mandated reporting requirements to the Congress. Section 4923 of the Balanced Budget Act of 1997, as amended by section 931 of the FY 2001 Consolidated Appropriations Act and by Section 1(c) of the Public Health Service Act Amendment for Diabetes, states:

Report on Diabetes Grant Programs

- "(a) Evaluation. The Secretary of Health and Human Services shall conduct an evaluation of the diabetes grant programs established under the amendments made by this chapter."
- "(b) Reports. The Secretary shall submit to the appropriate committees of Congress
 - (1) an interim report on the evaluation conducted under subsection (a) not later than January 1, 2000, and
 - (2) a final report on such evaluation not later than January 1, 2007 "

The first mandated interim report was transmitted to the Congress in 2000. The current report, which has been prepared by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), was initially prepared to meet a January 2003 statutory reporting requirement to the Congress on this program. That reporting requirement has now been changed to January 2007, as a result of the President's signature into law of P.L. 107-360. The NIDDK is proceeding to issue the current report because it provides an important interim assessment of the program by external scientific experts, grant recipients, and NIDDK staff who have analyzed the associated scientific literature and other relevant data on the program. Moreover, the report contains a highly useful summary of research opportunities identified by external experts in the field. These opportunities can thus serve as a scientific guidepost in developing this program in the years ahead.

Front Cover

Photo Credits: American Diabetes Association and Juvenile Diabetes Research Foundation International

Back Cover

Photo Credit: Over Cabrera and Camillo Ricordi, University of Miami, Diabetes Research Institute

REPORT ON PROGRESS & OPPORTUNITIES

Special Statutory
Funding Program for
Type 1 Diabetes
Research

CONTENTS

Executive Summary: Report on Progress and Opportunities	2
Assessment of the Special Statutory Funding Program for Type 1 Diabetes Research	16
Goal I: Identify the Genetic and Environmental Causes of Type 1 Diabetes	30
Goal II: Prevent or Reverse Type 1 Diabetes	44
Goal III: Develop Cell Replacement Therapy	62
Goal IV: Prevent or Reduce Hypoglycemia in Type 1 Diabetes	76
Goal V: Prevent or Reduce the Complications of Type 1 Diabetes	88
Goal VI: Attract New Talent to Research on Type 1 Diabetes	104
Future Opportunities for Type 1 Diabetes Research	116
Appendix 1: Allocation of the Special Statutory Funds for Type 1 Diabetes Research	126
Appendix 2: Supplemental Material on the Planning, Implementation, and Evaluation of the Special Statutory Funding Program	146
Appendix 3: Scientific Scope and Objectives of Major Special Statutory Funding Program Initiatives	158
Appendix 4: Selected Publications	194
Appendix 5: Summary Report of the April 2000 Advisory Panel Meeting	202
Appendix 6: Summary Report of the May 2002 Advisory Panel Meeting	206
Appendix 7: Abbreviations	230
Acknowledgements	232