Appendix 2

SUPPLEMENTAL MATERIAL ON THE PLANNING, IMPLEMENTATION, AND EVALUATION OF THE SPECIAL STATUTORY FUNDING PROGRAM

This appendix provides additional information on diabetes research plans and reports, and research conferences and workshops that are discussed in the Assessment chapter. In addition, the evaluation methodology that was used to develop this report is described.

1998 Administrative Plan for the Special Type 1 Diabetes Research Funding Program

In January 1998, the Director, NIH, submitted to HHS an administrative plan for the use of funds provided by the Balanced Budget Act of 1997 (P.L. 105-33) for type 1 diabetes research. The overall objective of the plan, formulated through meetings with both NIH and HHS components and the external diabetes research community, was to promote innovative, clinically relevant, and multidisciplinary research on type 1 diabetes. Particularly crucial to this initial plan were recommendations emanating from a 1997 trans-NIH symposium, "Diabetes Mellitus: Challenges and Opportunities," which was sponsored by the Director, NIH, along with nine institute directors. In addition, the chairmen of four working groups from this conference (i.e., "Type 1 Diabetes—Etiology and Pathogenesis," "Therapy," "Microvascular Complications," and "Macrovascular Complications") were involved in formulating this initial research plan for the special statutory funding program.

The special type 1 diabetes research initiative was expected to bring the best research talent, the most promising research ideas, and the most technologically advanced research tools to bear on combating type 1 diabetes, with particular attention to clinical and therapeutic issues. In addition, a budget strategy was developed to stratify the deployment of funds, so that a commitment base would not be built up in FY 1998 that would preclude funding of emerging scientific opportunities in the later years of the program. Within the overarching scientific and budgetary goals of the program, a plan was developed to support the immediate pursuit of highly promising, innovative science through trans-NIH research solicitations; the establishment of a CDC National Diabetes Laboratory; the development of approaches to exploit other areas of high scientific priority through small, 1-3 year funding strategies; the encouragement of technology development and application to exploit scientific opportunities through 1-year funding commitments; and the further pursuit of initiatives supported in the early years that proved most successful.

1999 Diabetes Research Working Group Strategic Plan

The Congress established the Diabetes Research Working Group (DRWG), as an independent panel of scientific experts from academia, industry, voluntary organizations, and the NIH, through Senate and House report language accompanying the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 1998. The DRWG was charged with the development of a comprehensive plan for NIH-funded diabetes research efforts. This plan covered all aspects of diabetes research, including both type 1 and type 2 diabetes.

The DRWG identified five "Extraordinary Research Opportunities"—Genetics, Autoimmunity and the Beta Cell, Cell Signaling and Cell Regulation, Obesity, and Clinical Research and Clinical Trials of Critical Importance. In addition, "Special Needs for Special Problems," which included diabetic complications, optimizing glucose control, and others, and "Resource and Infrastructural Needs" were addressed. The full DRWG report, "Conquering Diabetes: a Strategic Plan for the 21st Century," can be accessed at the NIDDK website (www.niddk.nih.gov/federal/dwg/fr.pdf). Since its completion in 1999, the plan has greatly enhanced the framing of diabetes initiatives at the NIH, including the Special Statutory Funding Program for Type 1 Diabetes Research. An update on new opportunities, scientific advances, and research progress made since issuance of the DRWG report was prepared in 2002 (http://www.niddk.nih.gov/federal/dwg/2002/dwg02.htm).

2000 Interim Evaluation Report on the Special Type 1 Diabetes Research Funds

In response to the Balanced Budget Act of 1997 (P.L. 105-33) that originally established the Special Statutory Funding Program for Type 1 Diabetes Research, an interim evaluation report was submitted to the Congress in 2000. Although it was premature at that time to assess scientific accomplishments of the special funding program, the report evaluated the planning and implementation process that guided the use of the special funds. The full report is posted on the NIDDK website (www.niddk.nih.gov/federal/initiative.htm).

2000 Advisory Meeting Report

An April 2000 advisory meeting of scientific and lay experts on type 1 diabetes was convened to advise the NIH and CDC on re-deployment of funds from P.L. 105-33 that became available in FY 2001. The recommendations of this panel (see Appendix 5) offered opportunities for participation in high-priority type 1 diabetes research by many components of the NIH and CDC. When the special statutory funding program was increased in amount by P.L. 106-554, the advice of this panel became instrumental in developing a strategy that was responsive to critical research needs and opportunities identified by the scientific community.

2001 Administrative Plan for the Special Type 1 Diabetes Research Funding Program

In February 2001, the Acting Director, NIH, submitted to HHS an administrative research plan for the expanded special funding program provided by the FY 2001 Consolidated Appropriations Act (P.L. 106-554). This plan, developed through consultation with NIH and other HHS components and the diabetes research community, clearly articulated the six broad research goals that frame the special program: identify the genetic and environmental causes of type 1 diabetes; prevent or reverse type 1 diabetes; develop cell replacement therapy; prevent or reduce hypoglycemia in type 1 diabetes; prevent or reduce the complications of type 1 diabetes; and attract new talent to research on type 1 diabetes. Through this careful priority-setting process, the NIH developed a scientifically-meritorious research plan that was within the budgetary targets and that complemented research initiatives launched with the P.L. 105-33 funds. Importantly, budget flexibility was maintained to support modifications during the later years of the program as science developed, and to address unanticipated needs or sudden shifts in focus that would optimize the use of the special funds for the benefit of type 1 diabetes research. Advice garnered from the April 2000 Advisory Meeting was invaluable in prioritizing the allocation of the increased funds provided for FY 2001-2003.

1997 Diabetes Mellitus: Challenges and Opportunities

(September 4-5, Bethesda MD, sponsored by the NIH Office of the Director, NIDDK, NCRR, NEI, NHGRI, NHLBI, NIA, NIAID, NICHD, NINDS) Diabetes is a multi-faceted, complex disease that directly affects many of the body's organ systems. This trans-NIH symposium brought together leading experts in diabetes and related fields to examine the state of the science and identify research gaps and opportunities that could be pursued across the NIH. Working groups convened to develop specific, in-depth recommendations on five topics of critical importance: Type 1 Diabetes—Etiology and Pathophysiology; Type 2 Diabetes—Etiology and Pathophysiology; Therapy; Microvascular Complications; and Macrovascular Complications. Cross-cutting recommendations from these groups included: expand research resources and facilities, such as tissue repositories and research databases, to give diabetes investigators necessary tools; develop new research methods and measures to foster diabetes research; pursue the development of clinical trials of potential therapies for diabetes and its complications; ensure a cadre of talented diabetes researchers by intensifying research training and career development efforts; foster translational research to enhance the timely transfer of important advances in diabetes research to the practice of medicine; develop new modes of interaction among academia, the NIH, and industry to foster diabetes research; and continue the planning process for diabetes research, for example through future workshops and conferences that could help guide program planning efforts and develop standardized research measures and assays.

1998 Expert Panel on Immune Tolerance

(February, Bethesda MD, sponsored by NIAID) Developing methods to achieve immune tolerance has the potential to halt the autoimmune destruction of beta cells in type 1 diabetes and prevent immune-mediated rejection of transplanted islets. Leading investigators in basic and clinical immunology convened to discuss plans for accelerating research on immune tolerance. Among the plans endorsed by this panel were recommendations for the creation of interactive, multi-institutional research programs that bring together experts in relevant basic and clinical disciplines to conduct large-scale research that cannot be accommodated within a single institution. Further, the panel advised the inclusion of mechanistic studies in conjunction with clinical trials and the establishment of immunology cooperative study groups to provide a central resource for the development of standardized assays and the identification and validation of surrogate markers of disease.

1998 Working Group on Cellular and Molecular Mechanisms of Diabetic Cardiomyopathy

(July 16, Bethesda MD, sponsored by NHLBI) Diabetes significantly increases an individual's risk of illness and death from cardiovascular disease. A panel of scientific experts reviewed the state of knowledge and research in diabetic cardiomyopathy and made recommendations for future research initiatives. The panel supported multidisciplinary, collaborative research on the cellular and molecular mechanisms of diabetic cardiomyopathy, the development of animal models that better simulate human disease, clinical research to characterize the epidemiology and pathophysiology of diabetic cardiomyopathy, and clinical trials to test novel interventions.

1998 *Etiology of Type 1 Diabetes

(August 31-September 1, Washington DC, sponsored by NIAID, NIDCR, NIDDK, JDRF) Although there is known to be a genetic component to type 1 diabetes, genetic predisposition does not fully account for development of this disease. This workshop reviewed evidence for viral infections or other environmental factors that may trigger type 1 diabetes. Scientists with expertise in the development of diabetes recommended that research

efforts be launched to identify those at high risk of type 1 diabetes, to understand the environmental factors and natural history of the disease, and to test potential interventional agents. Participants also encouraged the development of training and career advancement mechanisms to recruit new researchers into the field of diabetes research.

1999 *Advances in Neurobiology: A Key to Understanding Diabetic Neuropathy

(September 14-15, Bethesda MD, sponsored by NIDDK, NINDS, JDRF) Despite recent advances in the management of diabetes, neuropathy remains one of the most troubling complications of diabetes and constitutes a major public health problem. A workshop was held to re-examine the pathophysiology of diabetic neuropathy in light of recent advances in neurobiology. The goal of the workshop was to bring together investigators from the diabetes and neuroscience communities to examine new insights into the molecular and cellular biology of the neuron in the setting of diabetes. Researchers discussed new advances, highlighted potential areas of research that could lead to new therapies, and encouraged collaborations between neuroscientists and diabetologists.

1999 Imaging the Pancreatic Beta Cell

(April 19-20, Washington DC, sponsored by NIDDK, JDRF) Type 1 diabetes is characterized by an inadequate mass of functional pancreatic islet cells; yet, without the ability to visualize these cells in an animal or human, many questions of the natural history of the disease remain to be answered. This meeting brought together scientific experts in the fields of beta cell biology and imaging technology for discussions on the potential impact of new imaging technologies on understanding and managing diabetes. Participants advocated funding support for exploratory, interdisciplinary research that would jump start new approaches and attract new research talent to the imaging field.

1999 Gene Therapy Approaches for Diabetes and Its Complications

(November 8-9, Rockville MD, sponsored by NIDDK, NCRR, NHLBI, NIAID, ADA, JDRF) As technology for introducing new genes into cells has been improving, the disease targets for gene therapy have expanded beyond traditional genetic diseases to chronic diseases such as diabetes. Investigators met to discuss their results using gene therapy approaches to treat diabetes in animal models and human patients. The workshop recommended support for research efforts in four key areas: insulin expression in tissues where the hormone is not normally produced; interference with the autoimmune destruction of beta cells in type 1 diabetes; creation of surrogate beta cell lines for transplantation; and treatment of macrovascular and microvascular complications of diabetes.

1999 Workshop on Oral Diseases and Diabetes

(December 6-7, Washington DC, sponsored by NIDCR) Oral complications, including gum disease, salivary dysfunction, mucosal infections, and neurological problems of taste and smell, are major health problems in diabetic individuals. This workshop served as a forum for evaluation of the state-of-the-science on diabetes and oral health. Recommendations for future research that arose from this meeting included more study of the oral microbiology and immunology of diabetes.

2000 *Hypoglycemia and the Brain

(September 7-8, Washington DC, sponsored by NIDDK, NINDS, NICHD, NASA, ADA, JDRF) Episodes of severe hypoglycemia are a major obstacle in the management of diabetes and prevention of long-term complications. Further, hypoglycemia confers a risk of loss of consciousness, coma, and potential brain injury. This workshop was organized to review what is known about the brain's response to metabolic changes, to set research priorities for future efforts, and to stimulate research on the molecular and cellular mechanisms

by which hypoglycemia injures and kills neural cells. The participants identified several critical areas of research opportunity, including the need to develop strategies to promote glucose sensing by the brain and to restore the counter-regulatory hormonal responses in type 1 diabetes.

2000 Stem Cells and Pancreatic Development

(April 10-11, Bethesda MD, sponsored by NIDDK, ADA, JDRF) Stem cells, which are capable of self-renewal and differentiation into multiple cell lineages, have therapeutic potential for the treatment of diabetes. Researchers met to discuss issues in isolating and characterizing pancreatic stem cells that have the ability to reconstitute all pancreatic cell types. Among the recommendations that emerged from this workshop was the establishment of research alliances (e.g., consortia) of investigators from the stem cell biology, developmental biology, and diabetes research fields and the development of incentives to attract and train new clinical investigators in the fields of endocrinology and stem cell biology.

2000 Genetics of Diabetic Retinopathy

(September 21-22, Bethesda MD, sponsored by NEI) Diabetic eye disease—retinopathy—is a common, long-term complication of diabetes. A multidisciplinary group of scientists met to explore whether advances in genetic research could increase the opportunity for understanding the genetic predisposition underlying the development and/or progression of diabetic retinopathy. The group identified several high-priority recommendations for facilitating future research, including ancillary studies to identify the retinopathy phenotype in existing genetics studies; the support of interdisciplinary, collaborative research to evaluate the genetics of diabetes and its complications; the development of new research reagents and tools, such as improved animal models and microarray resources; and the recruitment of geneticists to work in vision research.

2000 Genetics of Type 1 Diabetes

(November 20, Rockville MD, sponsored by NIDDK, JDRF) Prior to this meeting, three genome-wide scans for type 1 diabetes genes had led to the identification of several chromosomal loci that showed evidence of harboring a diabetes susceptibility gene. Experts in the field of type 1 diabetes genetics met to explore the establishment of a collaborative effort on understanding the genetic basis of type 1 diabetes. As a result of this meeting, the Type 1 Diabetes Genetics Consortium was formed to pursue large-scale genetics research beyond the means of a single investigator study.

2001 *Pancreatic Development, Proliferation, and Stem Cells

(October 18-19, Bethesda MD, sponsored by NIDDK, ADA, JDRF) Replacement or regeneration of the pancreatic beta cells lost in diabetes holds promise as future therapeutic interventions for the treatment of this disease. Investigators from multiple disciplines doing cutting-edge research in developmental biology of the pancreas, islet cell biology, and stem cell biology met to discuss new insights into this rapidly developing field. Participants expressed support for the generation of essential reagents, assays, and a database of islet cell development and function, for research on the molecular mechanisms of islet cell neogenesis, proliferation, and programmed cell death, and for basic research on mouse and human stem cell biology.

2001 *Etiology and Epidemiology of Early Autoimmune Type 1 Diabetes in Humans

(October 25-26, Alexandria VA, sponsored by NIDDK) Large-scale epidemiological studies will be required to fully elucidate the complex interactions of genetics and environment that trigger type 1 diabetes. Researchers met to guide the NIH in the design of meaningful studies for understanding the immunologic mechanisms of diabetes. Meeting participants agreed on the need

for a large-scale, cooperative trial that can screen sufficient numbers of at-risk patients, and for standardized assays and centralized laboratory and storage resources to facilitate data collection.

2001 *Beta Cell Biology in the 21st Century

(November 26-28, Bethesda MD, sponsored by NIDDK, ADA, JDRF) Loss or dysfunction of insulin-producing pancreatic beta cells is central to the development of diabetes. This workshop convened beta cell biology researchers to assess the state of the science in beta cell structure, function, and physiology and to discuss ways to advance knowledge of the complex signaling pathways that govern beta cell function. Such research will facilitate the search for new therapies to prevent and treat diabetes. Participants identified key scientific questions that will guide future research in this field, including: definition of the factors required for maintenance of differentiated beta cells; identification of signaling cascades and networks within the beta cell and among beta cells and other cells of the pancreatic islets; understanding the minimal requirements for engineering a surrogate beta cell; and the application of genomics, proteomics, and other emerging technologies to the study of the beta cell.

2001 *Encapsulation and Immunoprotective Strategies of Islet Cells

(December 6-7, Washington DC, sponsored by NIDDK, NCRR, NASA, JDRF) Encapsulation of transplanted islet cells holds promise as a means of preventing rejection by the body's immune system. Workshop participants met to review the current state of encapsulation technology and to develop a strategy for future research in this area. Two high-priority issues were identified as a result of this meeting: the need for successful animal studies for further evidence and ultimate validation, and standardization of capsule materials and implantation procedures.

2002 *EDIC Autonomic Neuropathy Advisory Group Meeting

(May 29, Bethesda MD, sponsored by NIDDK). Diabetic autonomic neuropathy is a clinically significant outcome of diabetes with serious impact on quality-of-life, morbidity, and probably mortality. Yet, it is very much an uncharted discipline in diabetes research. The DCCT/EDIC cohort may provide an excellent opportunity to conduct research on autonomic neuropathy due to the extent of existing data collection and length of follow-up of these patients. Experts were convened to discuss the clinical importance of various forms of diabetic autonomic neuropathy, including gastroparesis, diabetic diarrhea/constipation, gall bladder dysfunction, bladder dysfunction, sexual dysfunction, orthostatic hypotension, cardiac sudden death, sweating dysfunction, and hypoglycemia unawareness. The advisory group suggested new studies to measure cardiovascular autonomic neuropathy with consideration given to using Holter monitors to measure RR intervals, perhaps with up to 24 hour blood pressure monitoring. In addition, the group recommended using the saved biologic samples of the DCCT/EDIC participants to measure several suggested markers and predictors of neuropathy.

* Supported in part by the Special Statutory Funding Program for Type 1 Diabetes Research.

MAY 2002 EXTERNAL ADVISORY PANEL

Advisory Meeting

A critically important aspect of the final evaluation is input received from an external panel of 15 leading scientists and lay persons with expertise on type 1 diabetes research, which was convened by the NIH in May 2002. The panel was provided with details on the goals and accomplishments to date, or expected outcomes, of more than 65 major initiatives supported by or planned for the Special Statutory Funding Program for Type 1 Diabetes Research. The advisory group was not charged with performing a project-by-project analysis, especially for many of the smaller initiatives and for those funded in the early years of the program. Rather, the panel was asked to consider major initiatives made possible by the special funding program, as well as newly emerging areas of promise. Panel members were urged to identify the most innovative research ideas—both within and beyond the traditional diabetes field—that the NIH and CDC should emphasize as future efforts in type 1 diabetes research are developed. To the extent that flexibility exists in allocating the remainder of the special funds through FY 2003, the panel was invited to comment on current or planned initiatives.

Summary of Panel Evaluation

The panel expressed great enthusiasm for research coordination mechanisms—consortia, clinical trial networks, repositories, databases, and registries—that have been established, in whole or in part, with the special funds, and urged the development of additional programs of this nature. The importance of continuity of support for these valuable research resources and infrastructure was strongly emphasized. Several strategies for facilitating the maximal use of these resources were proposed. Significant ideas included the addition of ancillary studies to large clinical trials, an increase in coordination among the various research groups, and expansion of the core missions of some research consortia to encompass emerging issues of high scientific priority. In addition, the advisors were pleased with the support of innovative, high-impact research through funding of pilot and feasibility grants to individual investigators. They appreciated the success of solicitations issued with these funds in attracting new investigators and established investigators who were new to diabetes research. The initiatives undertaken were felt to maintain an appropriate balance between large-scale research programs and investigator-initiated research. Moreover, these Requests for Applications (RFAs) have been issued periodically throughout the duration of the special funding program to ensure that they attracted the best, most cutting-edge science. The advisory panel emphasized that it was not yet possible to fully assess the outcome of the special funding program in that many projects were recently or newly initiated, not all of the FY 2002 funds had been deployed, and funding plans for FY 2003 had not yet been finalized.

Use of Panel Evaluation

Specific evaluative comments of the advisory panel regarding initiatives in progress or planned as of May 2002 are provided in this report within the context of each scientific goal of the special funding program. Opportunities identified by the panel for future research on type 1 diabetes form the basis of the chapter on "Future Opportunities." The complete Meeting Summary and Panel Recommendations of the Advisory Panel are available on the NIDDK website (http://www.niddk.nih.gov/federal/planning/type1summary.pdf) and are provided in Appendix 6.

Survey Instrument

The NIDDK received approval from the Office of Management and Budget (OMB) to survey extramural scientists who received research grants supported by the Special Statutory Funding Program for Type 1 Diabetes Research from FY 1998-2000. The survey instrument (OMB No. 0925-0503) was distributed by electronic mail in July 2002 with a response period of 30 days. Potential respondents were informed of the voluntary nature of the survey and the confidentiality of their responses to the extent provided by law. Further, grantees were advised that information collected through the survey would not impact current or future grant funding decisions.

The grantee survey, entitled "Assessment of the Use of Special Funding for Research on Type 1 Diabetes Provided by the Balanced Budget Act of 1997 and the FY 2001 Consolidated Appropriations Act," posed nine questions:

1.(a.) Was this the first, independent, NIH-supported research grant on which you were the principal investigator? (b.) Was this your first grant, from any source, applicable to type 1 diabetes research?

2.(a.) Identify the major accomplishment(s) resulting from the research supported by this grant that impacts the understanding, prevention, treatment, or cure of type 1 diabetes or its complications. (b.) Describe the diagnostic, therapeutic, or clinical implications of the research. (c.) Discuss new opportunities or ideas in the field of type 1 diabetes research that emerged as a result of this research.

3. Describe new research tools or resources of value to the type 1 diabetes research community that were developed as a result of this funding.

4. Describe the impact of this grant on your career. If this was your first funding support related specifically to type 1 diabetes or to diabetes in general, indicate whether you have continued to pursue research on either type 1 or type 2 diabetes.

5.(a.) Did the research supported by this grant require IRB approval? (b.) Did the research supported by this grant involve large animals or non-human primates? (c.) Did this grant permit clinically-relevant research that you otherwise would not have been able to pursue? (d.) Did this grant permit innovative or high-risk research that you otherwise would not have been able to pursue?

6.(a.) Did the research supported by this grant allow successful competition for continued funding of the same line of research inquiry? (b.) If yes, what is the source of that funding (e.g. NIH, ADA, JDRF, other)? (c.) If the source of continued funding was an NIH grant, provide the grant identification number.

7. List the most significant publications, including manuscripts in press, that resulted from research supported in part or in whole by this grant.

8. List all patents or patent applications resulting from research supported in part or in whole by this grant.

9. Provide any other comments you have regarding the impact or value of this grant or funding source.

Grantee Survey Response Rate

The survey covered 141 grants and 33 administrative supplements to a total of 168 investigators for research awarded with the special statutory funds in FY 1998-2000. Of the full grants, 20 were in progress through the end of FY 2002 and seven through FY 2003. One grantee and one supplement recipient were known to be deceased at the time of the survey; current contact information could not be located for one grant recipient. Principal investigators returned a total of 93 responses, involving 79 grants and 14 supplements. (This number includes three grantees who responded to a pre-survey in January 2002 during development of the survey instrument.) Thus, the overall response rate for the survey of special type 1 diabetes grantees was 54.4 percent (93 responses/171 distributed surveys.)

Use of Survey Data

Information collected through the survey of special type 1 diabetes grant recipients was incorporated throughout this evaluation report. Results from questions on innovative or high-risk research (Q.5d.), and patents or patent applications (Q.8.) are presented in the "Innovative and Clinically-Oriented Research" section of the "Assessment" chapter. Quantitative data on IRB-approved research (Q.5a.), large animal use (Q.5b.), and clinically-relevant research (Q.5c.), are listed in Table 5 of the "Assessment" chapter. Data on the recruitment of new investigators to type 1 diabetes research (Q.1.) and the continuation of research funding (Q.6.) were incorporated in the "Recruitment and Support of Diabetes Researchers" section of the "Assessment" chapter. Descriptions of research accomplishments and new research resources (Q.2. and Q.3.) and citations of published research (Q.7.) were integrated with information collected from other sources (e.g., grant progress reports and searches of the scientific literature) and are reported in the context of the relevant goal (main text) or Appendix 4. Scientific advances may be quoted directly or paraphrased from survey responses without attribution or other indications of source to protect the confidentiality of the survey respondents. Representative comments that are generally indicative of the types of comments received regarding the impact of these grants on investigators' research or careers (Q.4.) and the value of this funding program in general (Q.9.) are quoted verbatim, though without attribution, in the "External Evaluation" section of the chapters for each scientific goal.

ARCHIVAL DATA

Budget Analysis

Budget data (see Table 2 of the Assessment chapter and Appendix 1) and lists of grants supported by the special statutory funds (Appendix 1) were provided by the NIDDK Office of Financial Management and Analysis and the CDC National Diabetes Laboratory. Assignment of research initiatives to one or more of the major scientific goals of the special funding program was made by NIDDK program staff.

RFA Outcomes

Information on the success rates of research solicitations supported in whole or part by the Special Statutory Funding Program for Type 1 Diabetes Research was obtained from data provided by the NIDDK Office of Financial Management and Analysis, and by searching the internal NIH IMPAC database that lists all NIH grant awards. Data on the number of new R01 and R21 grants awarded by NIH in FY 1998-2002 was obtained by searching the CRISP (Computer Retrieval of Information on Scientific Projects) database. Statistics on NIH-wide success rates of unamended NIH competing renewal (type 2) grants from FY 2000-2002 were provided by the NIDDK Division of Extramural Activities from a search of the internal IMPAC II Reporting Database.

Analysis of Grantee History

Successful grant resubmission rates were compiled with information obtained from the internal NIH IMPAC database. Grants awarded with special statutory funds from FY 1998-2000 were included in this analysis. Only grants with a project period end-date of September 29, 2002 or earlier were assessed. Data from the "Application Status Code" field were used to determine if a grant had been resubmitted and/or awarded. Grants that were resubmitted, but not awarded, also included grants that had been unscored or withdrawn.

The number of new NIH grantees was calculated from data collected from the internal NIH CGAF (Consolidated Grants Applications File) and public CRISP databases. Grantees were counted as "new" if they had not previously been the principal investigator on an independent NIH research grant (e.g., R01, R21, P01) or cooperative agreement (e.g., U01, U10, U24). For the purposes of this study, training and career development awards (i.e., F-, T-, or K-coded grants), R13 conference grants, or M01 center grants were not counted as prior independent research support. The rate of "new-to-diabetes" investigators was assessed by searching previous grant titles and abstracts for diabetes-related terms. Specific mention of diabetes (either type 1, type 2, or unspecified), pancreas, islets, beta cells, glucose homeostasis, or insulin action was counted as diabetes-related research. Research grants on complications of diabetes were considered diabetes-related only if the abstract specifically described the condition as a diabetic complication. This analysis does not account for prior independent research support, either diabetes-related or otherwise, from sources other than the NIH.

Literature Search

Personnel from the NIH library assisted in the design of a PubMed (www.ncbi.nlm.nih.gov) search strategy to retrieve scientific articles reporting research findings supported by the special funding program. The basic structure of the search for each research grant was YYxxxxx [ad] OR (YY [ad] AND xxxxx [ad]), where YY is the institute acronym and xxxxx is the five digit grant serial number (e.g., DK12345 [ad] OR (DK [ad] AND 12345 [ad])). This strategy does not provide a comprehensive list of all research accomplishments supported in whole or part by the special funds for several reasons. Some journals do not include specific grant citations and some authors cite overall NIH support without providing a specific grant number. Investigators may incorrectly cite grant support, leading to both under- and over-reporting of grant-related research. Moreover, given the relatively recent time frame of the special funding program, many significant research findings may still be in progress. In this regard, more than half of the grantee survey respondents reported manuscripts in preparation, in review, or in press.

Research findings identified through the search of the PubMed database were incorporated into the reports of scientific advances in the main text. Further, selected publications are listed in Appendix 4. These examples of published research advances are not meant to be construed as a final accounting of the research accomplishments of early grants sponsored by the special statutory funds as many of these research efforts are ongoing.