TWENTY-THIRD ANNUAL REPORT OF THE DIABETES MELLITUS INTERAGENCY COORDINATING COMMITTEE

FISCAL YEAR 1997

Dr. Richard Eastman

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INTRODUCTION

Section 429 of the Public Health Act requires the Diabetes Mellitus Interagency Coordinating Committee (DMICC) to submit an annual report to the Secretary, Health and Human Services, and the Director, National Institutes of Health (NIH). Authorized by P.L. 93-354, DMICC was established in 1974; its legislative authority is presented in Appendix A. DMICC is charged with coordinating those research activities of the NIH and other Federal agencies that relate to diabetes mellitus and its complications and to contribute to the adequacy and technical soundness of these activities by providing a forum for communicating and exchanging information.

DMICC is chaired by the Director, Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases. In FY 1997, Committee members represented 20 Federal organizations; a liaison member represented the American Diabetes Association.

ACTIVITIES

The Committee facilitates communication and collaboration among agencies that conduct or support diabetes-related activities, provides a mechanism for tracking the interactions, and collects data on diabetes-related expenditures by each agency. In FY 1997, the DMICC met on January 17. The DMICC is pleased to present the following summary of diabetes-related activities reported by its representative organizations.

ACTIVITIES OF MEMBER ORGANIZATIONS

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

NIDDK's Division of Diabetes, Endocrinology, and Metabolic Diseases is responsible for extramural research programs. The Institute's divisions of Intramural Research; Digestive Diseases and Nutrition; and Kidney, Urologic, and Hematologic Diseases support diabetes-related activities as well. Basic and clinical research (including large-scale trials), epidemiology, prevention, and education are being supported.

In FY 1997, NIDDK-supported researchers reported progress in several areas. For type I diabetes, new approaches to protect transplanted pancreatic islet cells from immunologic destruction were proposed, the existence of precursor cells to islet beta cells was established, and blood glucose monitoring devices were improved. In type 2 diabetes, an animal model resembling human diabetes was developed, a way was found to prevent obesity-related diabetes in animals, and exercise was shown to greatly improve insulin sensitivity in children of parents with type 2 diabetes. A causative mechanism was revealed for diabetic kidney disease in animals, and a by-product of insulin synthesis was shown to have the potential to protect against heart and nerve damage caused by diabetes.

The Diabetes Prevention and Treatment Initiative

In 1994, NIDDK began the Diabetes Prevention and Treatment Initiative, which encompasses opportunities in basic and applied research, clinical studies and trials, national multicenter trials, and a national education program.

Basic research. Basic studies are the largest individual component of NIDDK-supported diabetes research and undergird research in diagnosis and prevention. Areas of interest include the pancreatic beta cell, the achievement of normal blood glucose concentrations (euglycemia), genetics, and obesity. NIDDK recently issued a Request for Applications (RFA) to encourage research on the beta cell. For approaches to euglycemia, the Institute has planned a program that includes basic, clinical, and applied research. Growth and development of pancreatic beta cells; beta cell and islet survival in transplantation; the isolating, encapsulating, and implanting of beta cells and islets; and bioengineering of cells are all included, as are glucose sensors and insulin pumps. In FY 1998, NIDDK will conduct a workshop to address the developmental biology of beta cells and other cell types; a Program Announcement (PA) will be issued later.

Genetics appears to play a key role in diabetes. Regarding obesity, NIDDK has identified an opportunity to enhance support for research on the obesity:type 2 diabetes connection. A planned program would encourage research to (1) identify hormonal and metabolic factors that control fat distribution and the metabolic consequences of differing fat distributions; and (2) determine whether increased physical activity will improve the metabolic fitness of obese diabetic persons with or without weight loss. In 1997, NIDDK convened a scientific workshop on the brain-fat cell regulatory process. In 1998, the Institute proposes to support research on the molecular basis of energy balance through pilot grants and funding of novel research.

Clinical trials. The multicenter Diabetes Prevention Trial-l is studying whether low-dose insulin can prevent or delay type I diabetes in at-risk persons. Another large trial, the Diabetes Prevention Program, is investigating strategies to prevent or delay type 2 diabetes in people with impaired glucose tolerance or gestational diabetes; about half the enrollees will be minorities. In FY 1999, NIDDK plans to cofund a clinical trial to investigate the effect of intensive glycemic control on progression of coronary heart disease in people with type 2 diabetes (NHLBI is the initiator).

Epidemiology, prevention, and education. (1) NIDDK is conducting a long-term follow-up study to ascertain certain disease endpoints in the Diabetes Control and Complications (DCCT) cohort; that NIDDK-sponsored trial showed that type I patients consistently maintaining almost-normal blood glucose concentrations can prevent or delay complications. (2) The Institute is encouraging increased research efforts on the impact of diabetes in minority populations. (3) NIDDK has initiated a National Diabetes Outreach Program and a media campaign, "Do Your Level Best: Start Controlling Blood Sugar Today." (4) NIDDK, CDC, and private entities collaborated on a National Diabetes Education Program, which was launched on June 23, 1998.

Kidney disease and urologic complications. Diabetes is the most common cause of end-stage renal disease. NIDDK has developed a research plan to further understanding of the antecedents of kidney disease of diabetes, the kidney's response to injury, and ultimately to identify and test treatment and prevention strategies; an RFA was recently issued. Urologic problems are common; NIDDK issued an RFA to encourage research on diabetes's effect on the urinary bladder and erectile dysfunction.

Conference. In 1997, NIDDK held the "Diabetes Mellitus: Challenges and Opportunities" symposium, at which leading experts identified research gaps and opportunities. A detailed report was later developed that should provide a useful framework for future trans-NIH efforts in diabetes.

NIH-Wide Issues

Diabetes Research Working Group. Responding to a request from Congress, the NIH established a Diabetes Research Working Group on December 1, 1997. The Working Group is charged with submitting to Congress by November 13,1998, a comprehensive plan for NIH-funded diabetes research. The NIH Director appointed Dr. C. Ronald Kahn, director of the Joslin Research Laboratory in Boston, as chair.

The Balanced Budget Act of 1997. This act provides the Secretary, DHHS, with $150 million over 5 years (1998-2002) to support research on preventing and curing type 1 diabetes. Annually, $27 million will be transferred to NIH, $3 million to CDC. In FY 1998, the NIH issued RFAs to support research in achieving euglycemia, mechanical approaches to metabolic control, pathogenesis and therapy of complications, and immunopathogenesis. FY 1998 funds also will be used to supplement existing grants.

National Institute on Aging (NIA)

The NIA supports biomedical and behavioral research to improve the prevention of diabetes and its complications and the quality of life of older patients. The NIA cosponsors the Diabetes Prevention Program and is collaborating with N1DDK on two new research initiatives on preventing and treating diabetic complications.

Highlights. (1) Ongoing studies address how risk factors for vascular disease influence the synthesis and function of advanced glycosylated endproducts receptors and provide a molecular basis for future epidemiologic studies and treatment of diabetes- and age-related vascular disease. (2) Research in rats suggests that glucose intolerance and insulin resistance may relate more to diet than aging. (3) Experiments are examining the regulation of glucose transport in skeletal muscle and relationships between diet and insulin resistance. (4) Studies also focus on interventions to reduce abdominal fat and mediation of regional differences in body fat in type 2 patients.

National Institute of Allergy and Infectious Diseases (NIAID)

NIAID supports the applying of basic immunology to the clinical investigation of autoimmune diseases, such as type I diabetes, and to kidney and islet transplant.

Recent activities. NIAID's support for research on autoimmune diseases has significantly increased in the past year; it also continues to support the Diabetes Prevention Trial-I and actively participates in the trans-NIH working group on type I diabetes. NIAID has requested applications for the new "autoimmunity centers of excellence" program, which includes clinical trials and basic research.

Under an RFA on transplant tolerance, NIAID and the Juvenile Diabetes Foundation International (JDFI) funded four program projects. NIAID also issued a PA on autoimmunity and continued a PA on microbes in autoimmune and immune-mediated diseases. NIAID supports contracts for isolating and characterizing major histocompatibility complex- (MHC-) bound self-peptides found in autoimmune diseases. The Institute hosted "Basic to Clinical Transitions in Autoimmune Disease" and organized a meeting on "Vaccines and Insulin Dependent Diabetes Mellitus."

Future activities. (1) A meeting entitled "Vaccinations for Prevention and Treatment of Autoimmune Diseases" is scheduled as part of NIAID's 50th anniversary celebration. (2) The Institute intends to issue a Request for Proposals for "Clinical Trials and Clinical Markers for Immunologic Diseases." (3) With NIDDK and the JDFI, NLAID is planning a meeting on "Environmental Etiology of Type 1 Diabetes: Viruses and Other Factors." (4) NL`UD is co-sponsoring a meeting on "Linking Environmental Agents and Autoimmune Diseases." (5) The Institute will publish a brochure for the public: "Understanding Autoimmune Diseases."

National Institute of Arthritis and Musculoskeletal and Skin Diseases -- no report
National Institute of Child Health and Human Development (NICHD)

The NICHD funds research on preventing type 1 and type 2 diabetes as well as the behavioral elements of diabetes; much of the program focuses on gestational and neonatal aspects. NICHD now supports two centers in the multicenter trial (see NIDDK report) to delay or prevent type 2 diabetes in persons of increased risk

Research highlights. The NICHD remains in the forefront of research on the cause and prevention of type 1 diabetes, focusing on identifying antigens, antibodies, and major histocompatibility loci on chromosome 6 linked to type I diabetes. (1) The Institute is currently funding the largest study on the natural history of type I diabetes. Early results indicate that first-degree relatives of index cases of type I diabetes bear a high risk of diabetes. (2) Researchers are testing whether strict glycemic control of diabetes before conception and through pregnancy will improve outcomes. (3) To understand the importance of the insulin gene transcription factor BETA2 in pancreatic endocrine cell differentiation, mice lacking functional BETA2 were generated. Results indicate that proper islet structure influences blood glucose homeostasis. (4) Research indicates that obesity in children of diabetic mothers appears to relate to high maternal insulin requirements and high plasma blood glucose concentrations in late pregnancy. (5) Investigators have discovered that mild hypoglycemia clearly affects cognitive function in children aged 12-18 years with type I diabetes. This study also assesses the role that autonomic nervous system abnormalities play in changing cerebral blood flow during mild hypoglycemia.

Future activities. The NICHD will continue to emphasize research on preventing type 1, type 2, and gestational diabetes. The Institute will support studies on the basic and clinical aspects of the immunogenetics of type I diabetes and immunomodulation of the immune system's attack on pancreatic beta cells.

National Institute of Dental Research (NIDR)

NIDR supports research on the causes, prevention, diagnosis, and treatment of oral and craniofacial diseases and conditions, including the oral complications of diabetes. NIDR also supports research on the effects of oral disorders on diabetic metabolic control. NIDR support for diabetes research increased about 17% from FY96 to FY97.

Recent activities. Basic research has included the role of non-enzymatic glycation of extracellular proteins in periodontal diseases, impaired macrophage or monocyte function in diabetics, and destruction of gingival connective tissue in diabetics have been studied. In translational research, salivary gland dysfunction in diabetic animals has been examined. Clinical research has examined diabetes as a risk factor for periodontitis; the association of diabetes, periodontitis, and heart disease; and treating periodontitis in Southwest Native Americans with type 2 diabetes. (4) Behavioral and/or health promotional activity has included oral health and diabetes, glycemic control in older diabetics, and population-based approaches for oral health care.

Future activities. NIDR will support an Interagency Agreement with the Indian Health Service to study treatment of periodontitis in Native Americans with Type 2 diabetes. The Institute also plans to support a conference on oral health and diabetes; it will work with other NIH institutes as well as key nongovernmental associations.

National Eye Institute (NEI)

The NEI conducts and supports research, training, the dissemination of health information, and other programs concerned with blinding eye diseases, visual disorders, visual function, sight preservation, and special needs of the blind. Diabetic retinopathy is the leading cause of blindness in people aged 24 to 70 years.

Research highlights. (1) Aldose reductase may be critical to developing diabetic retinopathy. A potent new aldose reductase inhibitor has been created that prevents expression of vascular endothelial growth factor in long-term galactosemic rats. (2) Research in mice has found that retinal neovascularization (which causes blindness) is inhibited by lowering growth hormone and insulin growth factor levels in the **blood.**

Future activities. NEI plans to conduct and support basic research to better understand the pathogenesis of diabetic retinopathy and develop better methods of preventing, diagnosing, and treating it. The Institute will also continue to cooperate with the American Diabetes Association, through the National Eye Health Education Program, to increase public awareness of diabetes-related eye disease.

National Institute of General Medical Sciences (NIGMS)

The NIGMS supports research and research training in the basic biomedical sciences; knowledge derived helps research progress on specific diseases, including diabetes.

Current activity. NIGMS supports the Human Genetic Mutant Cell Repository, which has cell lines of patients with genetic disorders and of normal controls. In 1997, the Repository provided university researchers with cell cultures from patients with type I diabetes, maturity-onset diabetes in the young, diabetes mellitus and diabetes insipidus with optic atrophy, and from Pima Indians with diabetes mellitus.

National Heart, Lung, and Blood Institute (NHLBI) -- no report

National Institute of Neurological Disorders and Stroke (NINDS)

The NINDS conducts and supports research in complications of diabetes that involve the peripheral and central nervous systems (e.g., diabetic neuropathy, stroke).

Recent activity. (1) In a long-term clinical and epidemiologic study in the Rochester, Minnesota population, NINDS grantees found that about 2/3 of diabetes patients showed signs of neuropathy in tests (e.g., of nerve conduction) but only about 1/5 of those with good glycemic control did so. (2) Other NIND-supported studies are examining the pathogenesis of diabetic retinopathy, which likely has many causes.

Plans. (1) The Minnesota study has added a Native American population. (2) A NINDS-supported project seeks to find whether insulin-like growth factor can help reverse the metabolic effects of diabetes and thus be used to prevent or treat diabetic neuropathy. (3) Scientists will continue to investigate the relationship between diabetes and stroke. (4) The NINDS is participating in the RFA entitled "Pathogenesis and Therapy of Complications of Diabetes."

National Institute of Nursing Research (NINR)

NINR views diabetes as a model chronic condition whose onset and course can be modified by factors related to prevention, control, and self care.

Current activities. (1) NINR is supporting research to determine effects of metabolic control in youth aged 13-20 years; multiple physiologic, behavioral, and quality-of-life measures are being used. (2) Another researcher is collecting age-related normative values of autonomic function for youth and identifying the possible onset of disturbed autonomic function in youth with type 1 diabetes. (3) NINR investigators are trying to explain changes in autonomic nervous system function after kidney and pancreas transplant and the relationship of these changes to quality of life.

Future plans. NINR will continue to collaborate with NIDDK on preventing and managing diabetes in minorities. The Institute plans to continue diabetes-related research through investigator-initiated programs and support of the NDEP.

National Center for Research Resources (NCRR) *(from 1995 Report)*

NCRR creates, develops, and provides a broad range of technologies and resources necessary for investigators to conduct biomedical and behavioral investigations. Support is provided in biomedical technology, comparative medicine, clinical research, and research infrastructure.

Recent activities. (1) In a collaborative study that involved an NCRR mass spectrometry resource at Washington University in St. Louis and an NHLBI-supported investigator, a link was demonstrated between imbalances in carnitine metabolism and several abnormalities associated with diabetic polyneuropathy. (2) Researchers successfully allotransplanted isolated pancreatic islet cells obtained from an NCRR-supported resource to diabetic patients. (3) Other research includes a study of cerebral blood flow and metabolism in diabetic dogs and projects at the Regional Primate Research Centers exploring metabolic processes in obesity and the regulation of insulin secretion.

The General Clinical Research Centers support numerous clinical studies in diabetes. Recent projects have focused on 1) using insulin therapy in patients with islet cell antibodies to prevent overt diabetes; 2) differences between whites and African Americans in glucoregulatory mechanisms and insulin metabolism; 3) using the presence of islet cell antibody to predict type I diabetes; 4) using magnetic resonance spectroscopy to study glycogen metabolism in diabetic and healthy subjects; and 5) the role of amylin in developing abnormal carbohydrate metabolism.

Future activities. NCRR will continue to provide an array of multi-user resources to help investigators study the pathophysiology and treatment of diabetes.

National Center for Human Genome Research (NCHGR) -- no report

Division of Research Grants (DRG) *(from the 1995 Annual Report)*

DRG's Metabolism Study Section reviews a very large number of applications in diabetes. The section contributes to DMICC activity by helping to ensure the quality of both basic and clinical research. Highly qualified scientists from academia and the pharmaceutical and high-technology industries review the applications. The Metabolism Study Section reviews investigator-initiated grant applications (r01s) and First

Award (R29s) and fellowship (F32s) applications. A summary statement includes the comments of the various reviewers and also reflects the crux of the meeting discussion; the summary also addresses whether the issues of risk and impact. Such information helps NIDDK staff make an appropriate funding decision.

Agency for Health Care Policy and Research (AHCPR) -- no report

Centers for Disease Control and Prevention (CDC) -- no report

National Center for Health Statistics (NCHS) *(from the 1995 Annual Report)*

NCHS is the Federal Government's principal vital and health statistics agency. The NCHS has data on medical care use for persons with diabetes treated in hospitals, physician's offices, and nursing homes. Mortality data for diabetes from the national vital statistics system are based on death certificates.

Recent accomplishments and activities. The NCHS has continuously collected data for diabetes and other causes of death and released these data in various forms, including data tapes and the annual *Vital Statistics of the United States.* The agency has published provisional diabetes mortality data in *Monthly Vital Statistics Report.* NCHS has collected data on an ongoing basis through the National Health Care Survey; it has also supported the mid-course review of the *Healthy People 2000* objectives in priority area 22, Diabetes and other Chronic Disabling Conditions.

In the future, NCHS will analyze data from the Third National Health and Nutrition Examination Survey, including updated estimates of the prevalence of diagnosed and undiagnosed diabetes in the population based on sample oral glucose tolerance tests.

Food and Drug Administration (FDA)

FDA approves safe and efficacious agents for public use, an issue of great importance in diabetes care. In 1997, troglitazone was approved for patients with type II diabetes receiving insulin whose hemoglobin Ale levels remain unsatisfactory; the drug reduces insulin resistance and enhances insulin sensitivity. Since it became available, however, at least 35 cases of liver failure have been reported among the 600,000 patients receiving it; FDA has advised physicians to monitor liver function.

Therapeutic options for patients with type II diabetes have grown. Metformin was approved in 1995 as monotherapy or with other approved agents; unlike sulfonylurea and insulin, it does not promote weight gain. Acarbose was approved in 1996; this agent can decrease postprandial hyperglycemia by 30-50%. FDA has also recently approved becaplermin (Regranex Gel) for deep diabetic foot and leg ulcers. When used topically and combined with standard ulcer care, this drug, which is produced through recombinant DNA technology, can improve the chances of complete healing.

Future activities will involve continuing to work with pharmaceutical firms on insulin analogs, implanted programmable pumps for intraperitoneal insulin infusion, and the development of anti-obesity agents that not only can decrease hyperglycemia but also exert beneficial effects on associated hyperlipidemia and coronary heart disease.

Health Resources Services Administration (HRSA)

HRSA manages numerous health care systems development programs, all of which include, as appropriate, diabetes education, prevention, recognition, or treatment.

Programs. The Bureau of Primary Health Care (BPHC) funds about 730 community-based health center programs for special populations; all clinical programs include appropriate diabetes screening and treatment. The Bureau's National Hansen's Disease Center is expert in foot pathology; it has developed the Lower Extremity Amputation Prevention program and a patient empowerment program that trains patients and families to screen for diabetic neuropathy.

The Bureau of Health Professions administers several programs supporting education in the health professions. Diabetes management is fundamental in the training of primary care practitioners. The Maternal and Child Health Bureau (MCHB) of HRSA administers block grants to states; the awards support information programs, screening for childhood diabetes, and the development of programs for diabetes care. MCHB's Healthy Start Initiative, designed to reduce infant mortality by 50 percent in targeted communities, addresses diabetes in mothers and children.

The Office of Special Programs supports the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. Over 1,000 people received a pancreas transplant in 1996 to correct problems related to diabetes; 850 received a kidney at the same time. In 1997, HRSA and HHS launched a cooperative initiative with other organizations, including the American Diabetes Association, to educate people about the need for more organ donations.

Indian Health Service (IHS) *(From 1995 Annual Report)*

The IHS's goal is to foster collaborative strategies for primary, secondary, and tertiary prevention in all IHS/tribal/urban facilities through a network of 19 model projects and area diabetes coordinators.

FY 1995 highlights. In FY 1995, over 8,000 medical records of persons with type 2 diabetes were randomly audited in the yearly IHS Diabetes Care Audit. A report entitled "Evaluation of Services Provided by IHS Model Diabetes Program" was published. The Diabetes Program worked with NIDDK to develop a Southwest Indian Center to participate in the NIDDK multicenter trial to prevent type 2 diabetes; it also worked in the NIMBI Pathways feasibility study of obesity prevention in Native American children. Diabetes nutrition education print materials for Native Americans were developed, field tested, and distributed nationwide.

Veterans Health Administration (VHA)

Diabetes affects 15% of VHA patients. The VHA tries to decrease the prevalence of adverse health outcomes in veterans with diabetes by developing and monitoring accountability measures relevant to education, risk screening, and health outcomes.

Recent developments. (1) For FY 1997, independent contractors from the External Peer Review Program reviewed over 13,000 charts of veterans with diabetes to document specific kinds of care. (2) The VHA Clinical Practice Guidelines for Diabetes Mellitus were published in March 1997. (3) At the start of 1997, 28 of the 481 programs nationwide that were recognized by the American Diabetes Association were in the VHA, more than any other single nationwide payer or for-profit program had.

(4) A comprehensive study conducted by the National Center for Cost Containment in 1996 of 240,000 veterans with diabetes is currently being analyzed. (5) Efforts are ongoing to make glycated hemoglobin testing accord with the DCCT standard. (6) Three diabetes centers of excellence were funded based on the Juvenile Diabetes Foundation International/VA Research Partnership.

Future plans. Guidelines will be revised by summer 1998. Additional diabetes research centers of excellence will be funded. Quality improvement research initiatives will be funded (the QUERI project). Additional clinical accountability measures will be instituted.

Membership Roster

Chairman

Richard Eastman, M.D.
Director, Division of Diabetes,
Endocrinology, and Metabolic Diseases
National Institute of Diabetes and
Digestive and Kidney Diseases
National Institutes of Health
Building 31, Room 9A16
31 Center Drive, MSC 2560
Bethesda, MD 20892-2560
Phone: (301) 496-7348
FAX: (301) 496-2830
E-mail: eastmand@extra.niddk.nih.gov

Executive Secretary

Charles A. Wells, Ph.D.
Director, Diabetes Special Programs
National Institute of Diabetes
and Digestive and Kidney Diseases
Division of Diabetes, Endocrinology, and
Metabolic Diseases
Building 45, Room 5AN-24B
45 Center Drive, MSC 6600
Bethesda, MD 20892-6600
Phone: (301) 594-8812
FAX: (301) 480-3503
E-mail: wellsc@extra.niddk.nih.gov

Susan J. Blumenthal, M.D., M.P.H.
Deputy Assistant Secretary for Health
(Women's Health)
Assistant Surgeon General
Department of Health and Human Services
Office of Women's Health
Hubert Humphrey Building, Room 730B
200 Independence Avenue, S.W.
Washington, DC 20201
Phone: (202) 690-7650
FAX: (202) 401-4005

Floyd J. Brinley, Jr., M.D., Ph.D.
Director, Division of Immune and
Infectious Disorders
National Institute of Neurological
Disorders and Stroke
National Institutes of Health
Federal Building, Room 5A12
7550 Wisconsin Avenue
Bethesda, MD 20892-9160
Phone: (301) 496-6541
FAX: (301) 402-0302
E-mail: fb18u@nih.gov

Carolyn Clancy, M.D.
Acting Director, Center for Outcomes and Effectiveness Research
Agency for Health Care Policy and Research
6010 Executive Boulevard, Suite 300
Rockville, MD 20852
Phone: (301) 594-2829
FAX: (301) 594-3211
E-mail: cclancy@po3.ahcpr.gov

Elaine Collier, M.D.
Chief, Autoimmunity Section
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Solar Building, Room 4A20
6003 Executive Boulevard, MSC 7640
Bethesda, MD 20892-7640
Phone: (301) 496-7104
FAX: (301) 402-2571
E-mail: ec5x@nih.gov

Michael P. Davis, M.S.
Associate Director for Science Policy and Legislation
National Eye Institute
National Institutes of Health
Building 31, Room 6A23
31 Center Drive, MSC 2510
Bethesda, MD 20892-2510
Phone: (301) 496-4308
FAX: (301) 402-3799

Katherine M. Flegal, Ph.D., M.P.H.
Senior Research Epidemiologist
Centers for Disease Control and Prevention
National Center for Health Statistics
6525 Belcrest Road, Room 900
Hyattsville, MD 20782
Phone: (301) 436-7075 x202
FAX: (301) 436-3436
E-mail: KMF2@cdc.gov

Julia B. Freeman, Ph.D.
Centers Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institutes of Health
Building 45, Room 5AS-19F
45 Center Drive, MSC 6500
Bethesda, MD 20892-6500
Phone: (301) 594-5052
FAX: (301) 480-4543
E-mail: freemanj@ep.niams.nih.gov

Harriet L. Gordon, M.D.
Medical Officer, General Clinical Research
National Center for Research Resources
National Institutes of Health
One Rockledge Centre, Room 6030
6705 Rockledge Drive, MSC 7965
Bethesda, MD 20892-7965
Phone: (301) 435-0790
FAX: (301) 480-3661
E-mail: harrietg@ep.ncrr.nih.gov

Gilman D. Grave, M.D.
Chief, Endocrinology, Nutrition,
and Growth Branch
National Institute of Child Health
and Human Development
Center for Research for Mothers
and Children
Building 6100, Room 4B11
6100 Executive Boulevard, MSC 7510
Bethesda, MD 20892-7510
Phone: (301) 496-5593
FAX: (301) 480-9791

Judith H. Greenberg, Ph.D.
Director, Division of Genetics and
Developmental Biology
National Institute of General Medical
Sciences
National Institutes of Health
Building 45, Room 2AS-25
45 Center Drive, MSC 6200
Bethesda, MD 20892-6200
Phone: (301) 594-0943
FAX: (301) 480-2228
E-mail: greenbej@gm1.nigms.nih.gov

Maureen Harris, Ph.D.
Director, Diabetes Research Section
National Institute of Diabetes and
Digestive and Kidney Diseases
Division of Diabetes, Endocrinology,
and Metabolic Diseases
Building 45, Room 5AN-24E
45 Center Drive, MSC 6600
Bethesda, MD 20892-6600
Phone: (301) 594-8801
FAX: (301) 480-3503
E-mail: harrism@extra.niddk.nih.gov

N. Krish Krishnan, Ph.D.

Scientific Review Administrator,
Metabolism Study Section
Center for Scientific Review
National Institutes of Health
Two Rockledge Centre, Room 6164
6701 Rockledge Drive, MSC 7892
Bethesda, MD 20817-7892
Phone: (301) 435-1041
FAX: (301) 480-2067
E-mail: krishnak@erg.nih.gov

John P. Lanigan, B.S.
Health Insurance Specialist
Health Care Financing Administration
Office of Professional Relations
Hubert Humphrey Building, Room 435H
200 Independence Avenue, S.W.
Washington, DC 20201
Phone: (202) 690-7418
FAX: (202) 401-7438

Mary Leveck, Ph.D., R.N.
Scientific Program Administrator
National Institute of Nursing Research
National Institutes of Health
Building 45, Room 3AN-12
45 Center Drive, MSC 6300
Bethesda, MD 20892-6300
Phone: (301) 594-5963
FAX: (301) 480-8260
E-mail: mleveck@ep.ninr.nih.gov

Louis Emmet Mahoney, M.D., Dr.P.H.
Medical Consultant
Office of Public Health Affairs
Health Resources and Services
Administration
Office of the Administrator
Parklawn Building, Room 14-39
5600 Fishers Lane
Rockville, MD 20857
Phone: (301) 443-0458
FAX: (301) 443-2605
E-mail: lmahoney@hrsa.dhhs.gov

Dennis Mangan, Ph.D.
Director, Periodontal Diseases Program
National Institute of Dental Research
National Institutes of Health
Building 45, Room 4AN-32F
45 Center Drive, MSC 6402
Bethesda, MD 20892-6402
Phone: (301) 594-2421
FAX: (301) 480-8318
E-mail: dennis.mangan@nih.gov

National Center for Human
Genome Research
National Institutes of Health
Bethesda, MD 20892

Leonard M. Pogach, M.D.
National Program Director, Diabetes
Veterans Health Administration
East Orange Veterans Affairs
Medical Center
385 Tremont Avenue
East Orange, NJ 07019-1095
Phone: (201) 676-1000 x1693
FAX: (201) 677-4408

Andre J. Premen, Ph.D.
Director, Cardiovascular Aging Program
National Institute on Aging
Geriatrics Program
Gateway Building, Room 3E327
7201 Wisconsin Avenue, MSC 9205
Bethesda, MD 20892-9205
Phone: (301) 496-6761
FAX: (301) 402-1784
E-mail: premena@gw.nia.nih.gov

David M. Robinson, Ph.D.
Director, Vascular Research Program
National Heart, Lung, and Blood Institute
National Institutes of Health
Two Rockledge Centre, Room 10193
6701 Rockledge Drive, MSC 7956
Bethesda, MD 20892-7956
Phone: (301) 435-0545
FAX: (301) 480-2849
E-mail: drw@cu.nih.gov

Shiao-Wei Shen, M.D.
Medical Officer, Division of Metabolism
and Endocrine Drug Products
Food and Drug Administration
Parklawn Building, Room 14B-04
5600 Fishers Lane, HFD-510
Rockville, MD 20857
Phone: (301) 443-3520
FAX: (301) 443-9282

Faye L. Wong, M.P.H., R.D.
Associate Director of Diabetes Education
Centers for Disease Control and Prevention
Division of Diabetes Translation
4770 Buford Highway, NE, MS K-10
Atlanta, GA 30341-3724
Phone: (770) 488-5037
FAX: (770) 488-5966
E-mail: flw2@ccdddt1.em.cdc.gov

Interagency Coordinating Committees

Sec. 429. [285c—3] (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities;

the Secretary shall establish a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordinating Committee, and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Each committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the Committee is established, the Division Director of the Institute for the diseases for which the Committee is established, the Chief Medical Director of the Veterans' Administration, [1] and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers) and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each committee shall meet at the call of the chairman, but not less often than four times a year.

(c) each Committee shall prepare an annual report for—

(1) the Secretary;

(2) the Director of NIH; and

(3) the Advisory Board established under section 430 for the diseases for which the Committee was established, detailing the work of the Committee in carrying out paragraphs (1) and (2) of subsection (a) in the fiscal year for which the report was prepared. Such report shall be submitted not later than 120 days after the end of each fiscal year.

[1] The reference is deemed to be a reference to the Under Secretary for Health of the Department of Veteran Affairs. See section 302(e)(1) of Public Law 102—405 (106) Stat. 1985) and section 10(4) of Public Law 100—527 (102 Stat. 2641).