Pediatric Diabetes Research in Texas

An Initiative to Understand and Prevent Diabetes in Texas Children

Report of the Texas Pediatric Diabetes Research Advisory Committee

Presented to the Governor, Lieutenant Governor,
and Speaker of the Texas House of Representatives

December 2002

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Executive Summary

Diabetes has reached epidemic proportions in Texas. Not only are the personal and economic tolls rising, but the rate of onset of type 2 diabetes is accelerating. In the coming years, Texas will be disproportionately affected due to its rapid population growth and ethnic diversity. Especially troubling is that this onslaught is occurring in a vulnerable population—Texas youth. Our chief concern is that, conservatively, the number of youth diagnosed with type 2 diabetes stands to triple over the next 25 years—a huge change for any condition—if we do not act.

In the pediatric population, type 1 diabetes (previously called "juvenile diabetes") is increasing at a rate of three to five percent each year. It already is the second most prevalent chronic disease of childhood (after asthma). Type 2 diabetes, which until recently was found only in adults, now accounts for nearly half of pediatric diabetes diagnosed in some areas of the state. The growing numbers and the inherent problems in treating youth alarm pediatric diabetes specialists and other health care providers.

Although research capacities exist, Texas is woefully lacking in pediatric diabetes research funding, and its residents are dramatically and disproportionately affected by diabetes. Responding to this concern, the 77th Texas Legislature in 2001 mandated the creation of a Texas Pediatric Diabetes Research Advisory Committee to develop a plan to research pediatric diabetes and medical conditions associated with diabetes within the state. The members of this Committee are active in research, education, and advocacy.

A review of the impact of diabetes on the Texas economy and the health of Texans indicates that more than 1.3 million Texans (over six percent of the population) have diabetes, with costs exceeding $9 billion annually. Another 1 million Texans are at very high risk of type 2 diabetes, with impaired ability to use insulin. Projections based on available studies suggest a lifetime price tag of $500,000 (in constant dollars) in direct and indirect costs for the average young person diagnosed with diabetes. If the number of Texas youth diagnosed with diabetes continues to increase at the current rate through 2025, then we can expect the sum total of the lifetime medical costs to be $15 billion.

During the past year, members of the Texas Pediatric Diabetes Research Advisory Committee assessed the resources and talent of Texas institutions for potential pediatric diabetes research opportunities. As part of their comprehensive study, the Committee considered numerous research possibilities regarding the cause, treatment, and prevention of diabetes for inclusion in a state-supported research agenda for children with diabetes. (Appendix 1 includes a detailed description of the areas considered.)

Following thoughtful examination, members concluded that the most pressing need, underlying all other issues considered, was for standardized family data, medical histories, and biological specimens sufficient to permit essential scientific inquiry.

To meet that fundamental need for data to support Texas scientists in their efforts to understand and prevent diabetes in Texas children, the Texas Pediatric Diabetes Research Advisory Committee recommends that:

1) diabetes diagnosed before the age of 21 be listed as a reportable disease to the Texas Department of Health and
2) the Legislature support the creation of the Texas Pediatric Diabetes Research Resource.

By adopting the recommendation to designate diabetes as a reportable disease, Texas will gain the most accurate and complete record of the incidence of diabetes in children of any state in the nation. Confining reporting requirements to the 500-1000 newly diagnosed pediatric cases per year will impose limited demands on medical practitioners, while providing significant new data about patterns and causes of diabetes within family and ethnic groups and across various regions of the state.

The recommendation to establish a Texas Pediatric Diabetes Research Resource recognizes the pressing need for reliable medical information and biological specimens that can be used to map the magnitude of pediatric diabetes and the reach of its related problems in the state. The Resource, which would be coordinated across existing facilities, would provide a registry of information and a means of collecting and storing blood specimens for DNA and plasma for use in approved research work.

A childhood diabetes research resource would provide investigators within the state access to a significant source for biological and scientific research. Scientists could obtain information including coded historical, demographic, and medical financial data related to cases of pediatric diabetes. Scientists also could apply for access to stored DNA and plasma from children with new onset diabetes and their family members who volunteer to provide these samples.

Such a resource would move Texas to the forefront of scientific and clinical investigations in pediatric diabetes. State-supported efforts also would help secure more federal and private funding for pediatric diabetes research, which seriously lags behind other states considering the size of Texas and the magnitude of the disease in the state.

Texas—with its diverse population of children and a highly skilled and experienced core of pediatric diabetes medical professionals and scientists—has a unique opportunity to establish an international resource for pediatric diabetes research. A modest funding base for collecting information and samples that can be shared among leading academic institutions would support the work of many researchers across the state and help attract additional world-class researchers to Texas.

The physical, emotional, and economic costs to children with diabetes and their families grow each year. If the number of children with pediatric diabetes continues to multiply, Texas can expect additional costs in Medicaid, Medicare, and other support programs. If the state takes steps to slow the trend of diabetes developing in Texas children, we can expect to save some $1 billion for every 10 percent decrease. Failure to take these steps and make a substantial investment in such an effort is an option Texas cannot afford.

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Introduction

Diabetes and its debilitating complications are a growing concern to Texans. The state faces "perfect storm" conditions from the projected growth in diabetes over the next 25 years. Along with the growing population, we anticipate an even higher growth rate in the state's ethnic minority groups, all of whom are at increased risk of diabetes. As the Hispanic, Black, Asian American, and American Indian populations become a larger percentage of the state's population, we can expect to see more cases of type 2 diabetes, a disease which disproportionately affects ethnic minorities.

At the same time, and perhaps more alarming, type 2 diabetes is becoming more prevalent in children. And as more young Texans are becoming overweight, their risk of type 2 diabetes rises. In addition to the long-standing challenges of treating youth with type 1 (previously called "juvenile") diabetes, Texas faces formidable new hurdles as growing numbers of youth also are diagnosed with type 2 diabetes or need monitoring due to their risk, e.g., overweight, positive family history of diabetes, high blood pressure.

Since 1983, with the establishment of the Texas Diabetes Council, the Texas Legislature has actively supported efforts to promote prevention and treatment options to reduce the impact of diabetes in adults—a chronic disease that today affects more than 1.3 million Texans. Today, diabetes is one of Texas' most costly diseases.[1] By 1997, the estimated direct and indirect cost of diabetes in Texas was $9.2 billion—and projections for the next 25 years indicate that the disease will be a leading major public health challenge in the 21st century.

[1] Diabetes Research Working Group. Conquering Diabetes: A Strategic Plan for the 21st Century. National Institutes of Health, US Department of Health and Human Services. (NIH Publication No. 99-4398). 1999.

History of the Texas Pediatric Diabetes Research Advisory Committee

Facing the growing diabetes epidemic in the state's pediatric population, the 77th Texas Legislature in 2001 authorized the establishment of the Texas Pediatric Diabetes Research Advisory Committee (TPDRAC) in the Texas Department of Health.

The Committee was directed to:

1) develop a plan to research pediatric diabetes and associated medical conditions, assess the resources and talent of institutions in Texas as possible sites for research opportunities,
2) analyze the impact of diabetes on the economy of Texas and on the health of its residents, and
3) make recommendations to the Legislature and the Governor concerning research programs in pediatric diabetes and funding alternatives for the program.

The legislation specified that the Committee should include persons with experience, expertise, or special interest in diabetes. Positions were designated for representatives of the Texas Department of Health, the Juvenile Diabetes Research Foundation (JDRF), the American Diabetes Association (ADA), research professionals from Texas academic or biomedical research institutions, and representatives of the health care industry.

The Texas Diabetes Council solicited nominations from a variety of sources, including the chairs of pediatrics and of endocrinology of Texas' public and private medical schools. Nominations were sought for professionals in pediatric endocrinology, ophthalmology, child health and development, genetics, heart disease, and nervous system and immune system disorders. Following a review of the nominations, the Council presented a slate of recommended members and leadership positions.

As directed by Senate Bill 1456, the Commissioner of Public Health, with recommendations from the Texas Diabetes Council, appointed the presiding officer and 14 members to serve on the TPDRAC. Texas Executive Deputy Commissioner of Health Charles Bell, MD, named Morey W. Haymond, MD, as chair and J. Cornelius Brown, CHE, as vice-chair.

Texas Pediatric Diabetes Research Advisory Committee Members

By designated category, members include:

Texas Diabetes Council
Judith L. Haley, Houston

Juvenile Diabetes Research Foundation
William Riley, MD, Driscoll Children's Hospital, Corpus Christi
Kathleen Wyne, MD, PhD, UT Southwestern Medical Center, Division of Endocrinology, Dallas
Ming-Jer Tsai, PhD, Baylor College of Medicine, Department of Molecular and Cellular Biology, Houston
Christopher Newgard, PhD (resigned upon acceptance of post at Duke University)

American Diabetes Association
Maria C. Alen, MD, Texas A&M University System, Health Science Center, McAllen
Surendra K. Varma, MD, Texas Tech University Health Science Center/Department of Pediatrics, Lubbock

Diabetes research professionals
Craig Hanis, PhD, University of Texas HSC School of Public Health, Houston
Barbara J. Anderson, PhD, Joslin Diabetes Center, Harvard University; Houston
Daniel E. Hale, MD, UTHSC, Division of Pediatric Endocrinology, San Antonio
Stephen Ponder, MD, CDE, Driscoll Children's Hospital, Corpus Christi
Morey W. Haymond, MD, Baylor College of Medicine, Children's Nutrition Research Center, Houston
Stephen Katz, MD, UT Medical School, Immunology and Organ Transplantation, Houston
Craig Spellman, PhD, DO, University of North Texas, Texas College of Osteopathic Medicine, Fort Worth

Health care industry
J. Cornelius Brown, CHE, Southwest Medical Center, Dallas

Texas Department of Health
Sharilyn K. Stanley, MD, Austin

Meetings of the Advisory Committee

The Advisory Committee began deliberations with conference calls and posted meetings of the entire Committee on November 27, 2001, February 25, April 29, May 31, and August 1, 2002. The Committee complied with its legislative mandate to meet at least four times and use a professional facilitator.

In fulfilling its charge, the Committee set criteria by which to evaluate a wide array of approaches required to understand and prevent diabetes and its complications in Texas' children. These criteria for recommendations are identified in Appendix I.

The Growing Threat of Diabetes in Children

People with high blood sugar levels usually have either type 1 or type 2 diabetes. The onset of type 1 diabetes most commonly occurs in childhood and historically has been the most common form of diabetes in children—affecting about one in 400-500 children.[2]

Most children with diabetes in the United States have the type 1 form—with the possible exception of Texas. Within the last two decades type 2 diabetes has been diagnosed in the pediatric population, and the prevalence is increasing at alarming rates in Texas.[3,4] By 1999, the incidence of new type 2 diabetes diagnoses ranged between 8 percent and 45 percent, depending on geographic location. This increased prevalence is not due to improved detection. Practice site reports and some regional studies indicate nearly 50 percent of newly diagnosed cases of diabetes in children to be type 2 diabetes.[5,6]

Type 1 diabetes is an autoimmune disorder that destroys insulin-secreting cells in the pancreas and occurs disproportionately among children of European heritage. Type 2 diabetes occurs predominantly in children of Hispanic, Black, American Indian, or Asian heritage. Type 2 diabetes is the result of resistance of the body tissues to the effects of insulin and a resulting inability of the pancreatic beta cell to produce adequate amounts of insulin to overcome this resistance.

Pediatric Diabetes	
Type 1	**Type 2**
Historically the most common form in children	Less common in youth, but the risk and diagnosed cases are on the rise
Characterized by the body's inability to produce insulin due to the destruction of insulin-secreting beta cells in the pancreas	Characterized by the body's inability to use insulin effectively and an inability to produce adequate amounts of insulin; *aka* insulin resistance; commonly linked to obesity
Higher prevalence among persons of European heritage	Occurs predominantly in persons of Hispanic, Black, American Indian, or Asian heritage

[2] 1997-1999 National Health Interview Survey (NHIS), National Center for Health Statistics, Centers for Disease Control and Prevention.

[3] Ponder SW, Sullivan S, McBath G. Type 2 diabetes mellitus in teens. *Diabetes Spectrum* 13 (2), 2000.

[4] Fagot-Campagna A. et al. Type 2 diabetes among North American children and adolescents: an epidemiologic review and a public health perspective. *J Pediatr* 2000: 136:664-72.

[5] Kaufman FR. Type 2 diabetes mellitus in children and youth: a new epidemic. *Pediatr Endocrinol Metab* 15 (Suppl 2):737-44, 2002.

[6] Neufeld ND, Raffel IJ, Landon C, Chen YD, Vadheim CM. Early presentation of type 2 diabetes in low-income Mexican-American children. *Diabetes Care* 22:202-207, 1999.

Daily Demands Last a Lifetime

Children with diabetes—and their families—endure a physical, emotional, and economic toll. Activities in the daily life of a child with diabetes are overshadowed by the constant need to monitor blood glucose levels, ensure balanced intake of carbohydrates, and achieve the right combination of physical activity and adequate rest. Accomplishing safe and acceptable blood glucose control requires patient education and lifestyle changes. Learning about diet, insulin interactions, medications, and the impact of stress, puberty, illness, and physical activity on blood sugar is the first step to understanding the disease. Mastering medication administration and glucose self-monitoring are critical to maintaining normal glucose levels. The most challenging aspect of diabetes management is incorporating needed lifestyle changes into the daily routine. Diabetes takes no holiday.

A mother of two children afflicted with type 1 diabetes related the impact of this disease on her children.

"But isn't diabetes a disease for 'old people'?"

I remember asking that of our pediatrician, when he called that day 12 years ago—the day when our lives changed forever. How could my precious 10-year-old daughter have something so serious? And how could my 12-year-old son fall victim to the same disease only seven months later? We had no family history and no sense of the impact it would have upon our family.

At first, the hard part was testing blood four, five, or six times a day; taking three shots of insulin every day; treating low blood sugar emergencies, which are life-threatening, and high blood sugar episodes, which feel awful.

Other children could stay out on a summer night and play until dark; but not our children, who had to eat on schedule, sleep on schedule, and intersperse fun with "finger sticks" to see if they were on course.

Dance recitals, football games, basketball practice—all presented special challenges. SAT tests, sleep-overs, field trips—do-able, but tough. Missed class time for medical appointments and pre-meal testing became routine; no seats left at the cafeteria table or on the bleachers after a visit to the school nurse caused as many tears as the shots.

But insulin is not a cure; and the impact on families goes way beyond the drudgery and pain of the daily routine. Two-year-olds should be able to sleep through the night, not awakened to more sticking and poking. Twelve-year-olds should not have kidney damage. Twenty-five-year-olds should not be blind, incapacitated by strokes, plagued by numbness and pain and digestive disorders because of nerve injury. And 31-year-olds should not die in a mother's arms because diabetes has so profoundly damaged all their organs.

But that is what has happened to Bob, to Caroline, to Jill, to Danielle—and to countless other children. That is the reality of diabetes.

As the mother of two "emerging young adults" with diabetes, I recognize that the only remedy is a cure.

— Judith Haley

Much is known about the physical complications of living with diabetes, but children with diabetes also are at increased risk of major depression, anxiety disorders, and eating disorders.[7,8] Coping with these conditions adds stress to the child with diabetes, as well as to the family.

Successfully managing pediatric diabetes involves significant behavior change in both the child and the child's family. Adding a major mental stress to that existing challenge sets in motion a vicious cycle: compromised adherence to treatment leads to impaired health, followed by increased stress and expenses.[9] Accessing mental health treatment presents another hurdle for many families of children with diabetes. Barriers to obtaining counseling to help make needed behavior changes include: the stigma associated with depression, the lack of local mental health clinicians knowledgeable about health issues in youth with diabetes, the family's lack of mental health insurance coverage, as well as other economic constraints.[10]

Long-term studies following youth from childhood through adolescence and into young adulthood show that children with diabetes who experience psychiatric problems continue to experience problems as young adults.[11,12,13] Moreover, patients with both diabetes and psychiatric problems are at increased risk of poor adherence and, thus, of dangerously poor metabolic control. Ultimately, this means that these patients suffer increased risk of the progressive long-term complications of diabetes—which jeopardize the eyes, kidneys, and cardio-vascular system.[14] This vicious cycle of suffering and expense continues, as pediatric diabetes patients with both physical complications and psychiatric co-morbidities need more frequent and more expensive hospitalizations and health care services. These individuals also experience a compromised employment potential and quality of life during young adulthood.

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[7] Blanz BJ, Rensch-Riemann BS, Fritz-Sigmund DI, Schmidt MH. IDDM is a risk factor for adolescent psychiatric disorders. *Diabetes Care* 16: 1579-1587, 1993.

[8] Mayou R, Peveler R, Daview B, Mann J, Fairburn C. Psychiatric morbidity in young adults with insulin dependent diabetes mellitus. *Psychol Med* 21: 639-645, 1991.

[9] Bryden KS, Peveler RS, Stein A, Neil A, Mayou RA, Dunger DB. The clinical and psychological course of diabetes from adolescence to young adulthood: A longitudinal cohort study. *Diabetes Care* 24: 1536-1540, 2001.

[10] Coyne JC, Anderson BJ. The "psychosomatic family" reconsidered: Diabetes in context. *J Marital Fam Ther* 14: 113-123, 1988.

[11] Bryden KS *et al. ibid.*

[12] Wysoki T, Hough BS, Ward KM, Green LK. Diabetes mellitus in the transition to adulthood: Adjustment, self-care, and health care status. *J Dev Behav Pediatr* 13: 194-201, 1992.

[13] Jacobson AM, Hauser ST, Cole C, Willet JB, Wolfsdorf JI, Dvork R, Wolpert HA, Herman L, De Groot M. Social relationships among young adults with insulin-dependent diabetes mellitus: Ten-year follow-up of an onset cohort. *Diabet Med* 14: 73-79, 1997.

[14] Rydall AC, Rodin GM, Olmsted MP, Devenyi RG, Daneman D. Disordered eating behavior and microvascular complications in young women with insulin-dependent diabetes mellitus. *N Engl J Med* 336 (26): 1849-1854, 1997.

Lack of Data Limits Understanding

There is a pressing need for reliable data to understand the magnitude of diabetes in Texas. Diabetes is a critical chronic condition that can lead to disabling complications and premature death, but *it is not a reportable disease*. In the absence of systematic, centralized reporting, there is no way to know the number of new cases diagnosed each year or the accumulation of the total number of cases in any given year or over a number of years.

Limited projections can be made about the extent of diabetes based on published studies, but no population-based data are available to estimate accurately the occurrence and impact of diabetes on the youth of Texas. Neither the Texas Department of Health, nor the Texas Diabetes Council, nor the Centers for Disease Control and Prevention (CDC), nor the National Institutes of Health (NIH) have sufficient information to precisely assess the direct and indirect costs of this disease to their lives, their families, and our communities. The first US population-based study to estimate the incidence (new cases each year) and prevalence (the total number of cases in an area) of diabetes among children has been initiated by the CDC. Unfortunately, the six-site surveillance study does not include Texas, which is disproportionately affected by diabetes due to its large population and high number of ethnic minorities.

The summary projections included in this report rely on various sources that provide the current estimates of the diabetes burden in Texas. ”High validity” data sources include published scientific reports and CDC reports. “Mixed validity” reports include studies issued by pharmaceutical companies, insurance companies, health plans, the NIH, the state Children’s Health Insurance Program (CHIP), and Medicaid. Other resources include clinical laboratories and clinical experiences. Thus, the projections of diabetes in this report have some variances because of the limits of the estimates and available data. *Such limitations underscore the need for validated data.*

The following information details what has been reported to date about the cost of diabetes in adults, and extrapolations have been made to the children of Texas. In each case, the Committee attempted to delineate a range of confidences around these numbers. Consistent with NIH standards, this report considers children to be persons under 21 years of age.

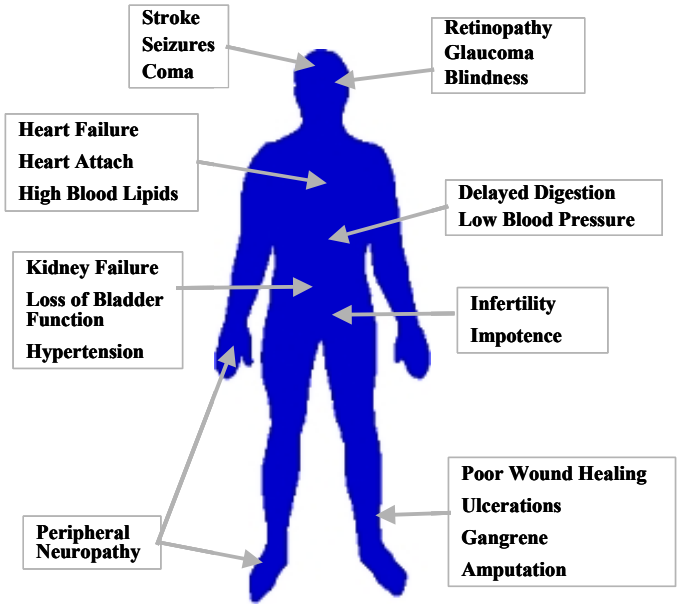
National Costs of Diabetes

Numbers of Americans Affected

At least 17 million Americans have diabetes and more than 200,000 people die each year of related complications.[15] Of all Americans with diabetes, nearly 6 million are unaware they have the disease because their condition has not been diagnosed. The cost of diabetes includes both the direct medical costs of the disease—physician services, hospital costs, home health services, education classes, medications, supplies, and testing materials—as well as the indirect costs. Indirect costs may include loss of work, income, or class time that results from the need of an individual and/or family members to attend medical visits, and permanent disabilities. Indirect costs also may result from frustration, burn out, discouragement, inconvenience, pain, discomfort, and depression.

Diabetes Complications Present Serious Physical Health Threats

The complications of diabetes are not always attributed to diabetes. Because hospital records and death certificates often fail to indicate diabetes as an *underlying* cause of the care or death, the true impact is underestimated. For example, an person dying of a heart attack related to chronic high cholesterol and poorly controlled diabetes may be listed as a death due to heart disease when, in fact, death was a complication of diabetes.



Diabetes Affects Many Body Systems & Daily Life

Complications that result from diabetes affect virtually every major system of the body. Diabetes is the leading cause of heart disease, blindness, renal (kidney) failure, and non-traumatic lower limb (toe, foot, and leg) amputation. It also is the leading cause of impotence and a major contributing factor for coronary artery disease, stroke, and large vessel disease – leading causes of death.

Kidney failure caused by diabetes can result in a need for life-sustaining dialysis and/or transplantation. Loss of sensation (peripheral neuropathy) and circulation problems in the small blood vessels, the capillaries, can lead to chronic foot ulcerations, gangrene and ultimately amputation of the foot and leg. Gastrointestinal and bladder problems due to neuropathy also have a significant impact on quality of life. In addition, the compromised condition of having a chronic degenerative disease creates increased risk of significant illness, even premature death, from common infections such as influenza and pneumonia.

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[15] www.cdc.gov/diabetes. Accesssed March 27, 2002.

Diabetes Deals Economic Impact

The financial cost of diabetes is staggering. Though a lack of uniform data leads to varied estimates from leading research organizations, there is consensus that the costs associated with diabetes are enormous.

The American Diabetes Association estimates that care for diabetes and its complications account for one in every six health care dollars spent. The total per capita costs of health care in 1997 for adults with diabetes was $10,071 compared to $2,699 for adults without the diagnosis.[16]

The congressionally mandated Diabetes Research Working Group reported that one in every 10 health care dollars and about one in every four Medicare dollars pays for health care for persons with diabetes.[17]

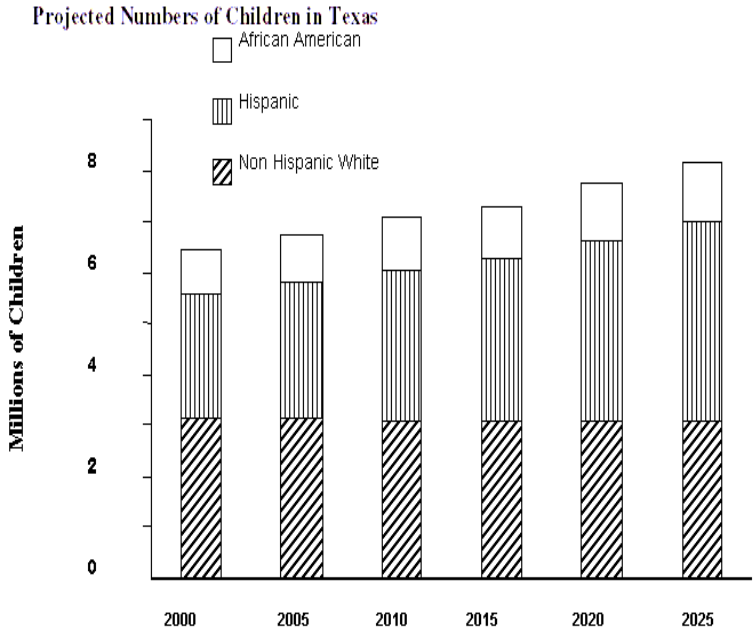
[16] American Diabetes Association. Economic consequences of diabetes mellitus in the US in 1997. *Diabetes Care* 21:296-309, 1998.

[17] Diabetes Research Working Group. Conquering Diabetes: A Strategic Plan for the 21st Century. National Institutes of Health, US Department of Health and Human Services (NIH Publication No. 99-4398), 1999.

Growing Number of Texas Children at Risk

Trends

For this report, the Committee used the population projections prepared by the US Census Bureau for the years 1995-2025 found at: http://www.census.gov/population/www/projections/stproj.html.



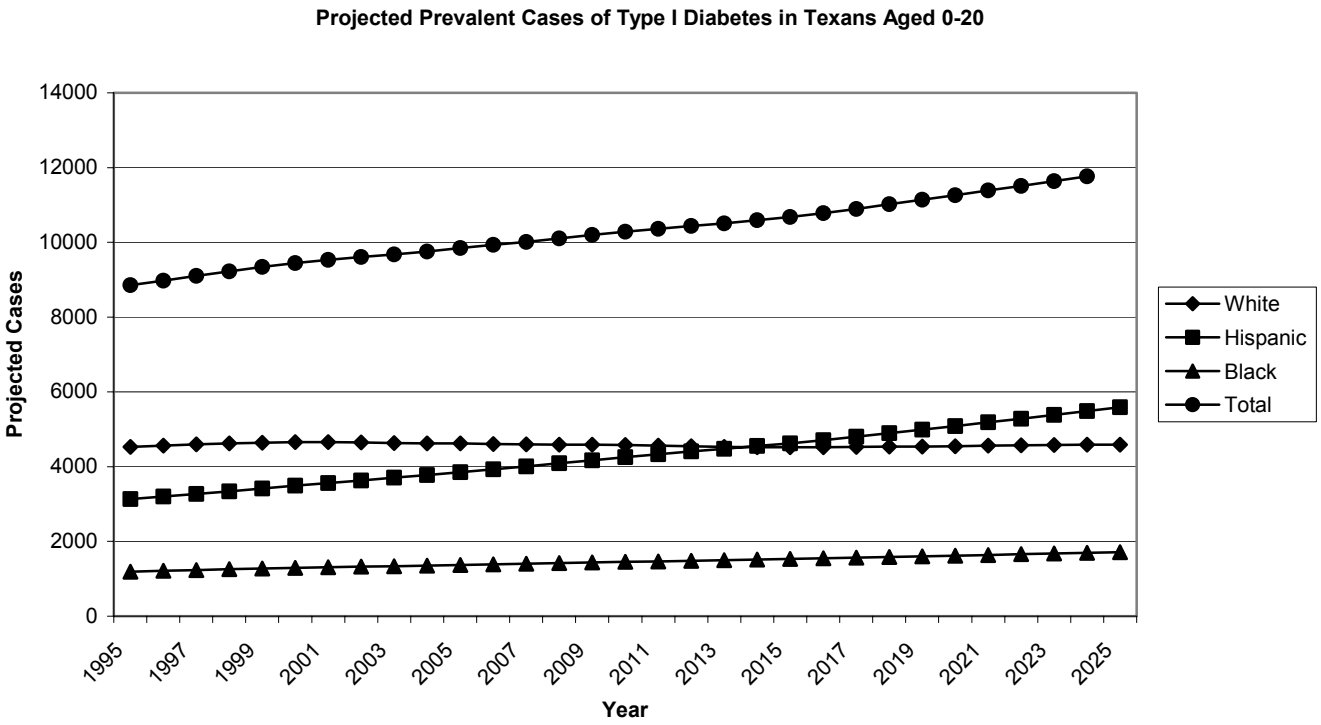
More than a million children will be born in or move to Texas over the next 25 years. Given current trends, the number of non-Hispanic white children will remain fairly constant, whereas the numbers of Black and Hispanic children will increase by 32 percent and 60 percent, respectively. Along with these increases, Texas can expect to see a rise in the number of children with type 1 or type 2 diabetes concentrated in the Hispanic and Black populations.

It is estimated that by 2025, Texas will have approximately 11,900 youth at or under age 20 years with type 1 diabetes, another 17,700 with type 2 and countless more at high risk of type 2 in later adult years. (A full description of the methods used to make the reported projections is found in Appendix VI.)

Type 1

The younger a child at the onset of type 1 diabetes, the more likely he or she will be to experience serious acute episodes—ketoacidosis and/or severe hypoglycemia (low blood sugar).[18] These youth also are quite likely to experience complications and premature death due to decades of living with diabetes after diagnosis. The overall prevalence of type 1 diabetes is between 1 in 400 and 1 in 500; that is already 10,000 Texas children. The rate of new cases (incidence) is assumed to be constant and the increased number of cases over time are related to population growth.

[18] Rewers A. *et al*. Predictors of acute complications in children with type 1 diabetes. *JAMA* 287(19):2511-8, 2002.



Type 2

Obesity is the major risk factor for new cases of type 2 diabetes. The percentage of overweight children has risen at an alarming rate over the last decade. The proportion of children at risk of overweight—i.e., having a body mass index (BMI) between the 85th and 95th percentile by national definitions—has increased from 15 to 22 percent. The percentage of overweight children measuring above the 95th BMI percentile rose from 5 to 11 percent between 1963–1975 and 1988–1994.[19] In the 1999-2000 National Health and Nutrition Examination Survey (NHANES), the rate of overweight children—i.e., BMI above the 95th percentile—has increased to nearly 15 percent.[20]

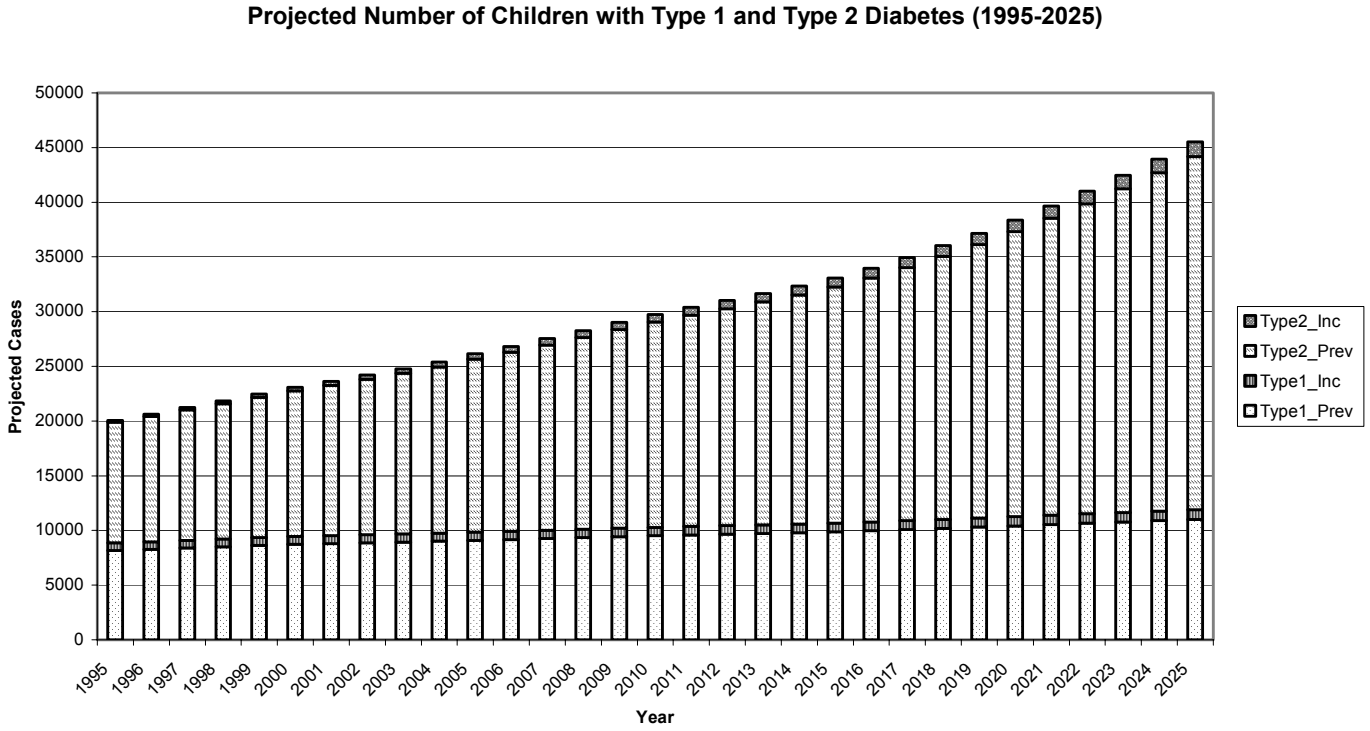
Associated with the increase in overweight among children, the number of newly diagnosed type 2 diabetes among youth is climbing from about five percent to 30 and 40 percent nationwide. Some pediatric diabetes practices in Texas clinics report that type 2 diabetes is now the prevalent type of newly diagnosed diabetes.

Youth with type 2 diabetes are disproportionately of Black, American Indian, or Hispanic heritage. However, type 2 diabetes is found in all racial and ethnic groups, including non-Hispanic whites and Asian Americans. They typically are overweight. Their immediate

[19] Health, United States, 2002, Overweight children and adolescents 6-19 years of age, according to sex, age, race, and Hispanic origin: United States, selected years 1963-65 through 1999-2000.

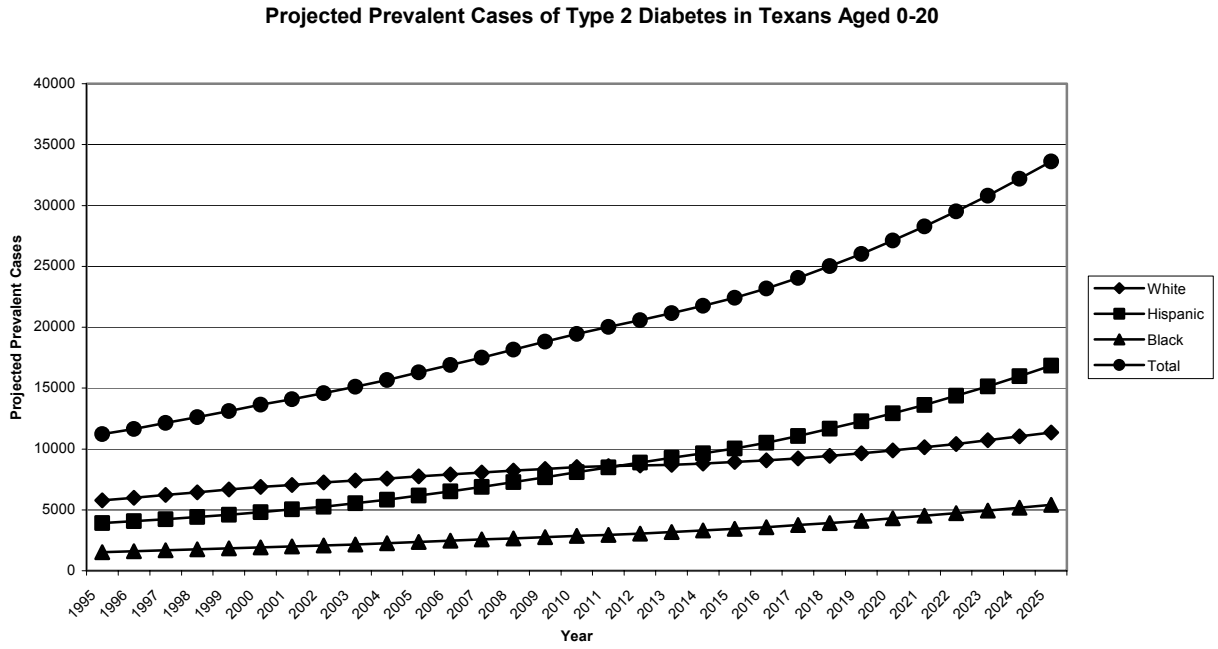
[20] Ogden CL, Flegal KM, Carroll MD, Johnson CL. Prevalence and trends in overweight among US children and adolescents, 1999-2000. JAMA 288:1728-32. 2002.

family members are usually overweight and may have type 2 diabetes. With the rising number of overweight children in every ethnic group, the rate of type 2 diabetes in youth and young adults also will increase in every group. Studies of severely overweight youth, regardless of ethnicity, show that over a fifth already have Impaired Glucose Tolerance, or "pre-diabetes."[21]



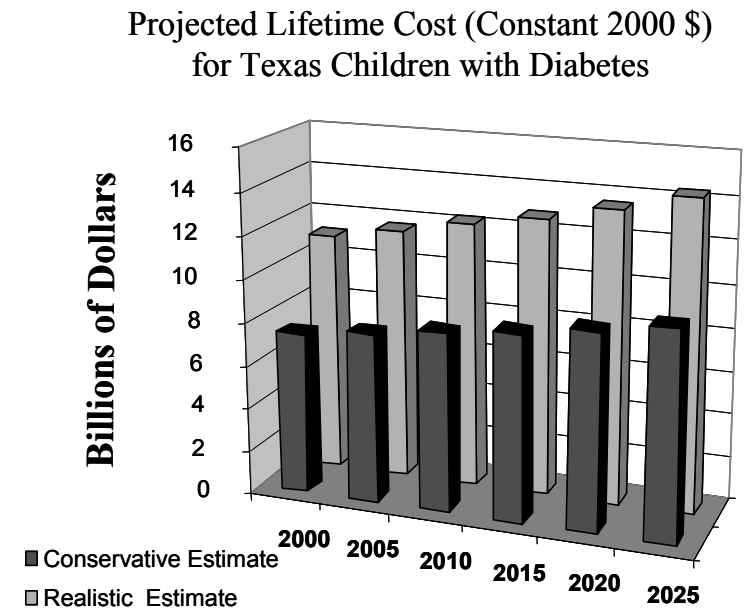
Conservative estimates from available data suggest that nearly 30,000 Texas youth will have diagnosed diabetes in the next 25 years. If there are no changes in this trend, the number of children with type 2 diabetes (the prevalence) will triple – a huge change for any disease.

[21] Gaezner H. Impaired Glucose Tolerance in obese children and adolescents. *N Engl J Med* 346(11):802-810, 2002.



Costs of Diabetes in Youth Multiply over Lifetime

Assuming that direct medical care costs (e.g., hospitalization, office visits) for diabetes in children are less than half that of adults with diabetes, the cost is more than $3,000 per year. Physicians estimate that a third of children with diabetes (usually type 1) require hospitalization at diagnosis. Given an average age of 12 years at diagnosis, each youth will require $27,000 (in constant 2002 dollars) of extra care. Having diabetes makes any sort of medical treatment more costly. A 1998 study revealed the escalating costs caused by diabetes and its complications. For example, kidney dialysis for a patient with diabetes cost $59,000 per year, compared to $31,000 for a person without diabetes. [22]



[22] Ruggeneti P *et al.* The nephropathy of non-insulin-dependent diabetes: predictors of outcome relative to diverse patterns of renal injury. *J Am Soc Nephrol* 9:2336-2343, 1998

The costs of care for diabetes escalate with increasing age and duration. Direct costs include hospital stays and office visits. Indirect costs for adults include lost work days and permanent disability as well as premature death. CDC information suggests that a person diagnosed with diabetes after age 24, and an average life expectancy of 60 years (a 34 year span of time), can expect to need $325,000-$500,000 for the direct and indirect costs of diabetes ($10,000-$15,000 per year). Each Texas youth who developed diabetes (average age 12 at diagnosis) in the year 2000 will incur an estimated $500,000 or more in costs over his or her lifetime.

Lifetime direct and indirect costs—much of which are borne by the State of Texas—range from $7 billion to $11 billion for children today and up to $14 billion for those with diabetes in 2025. These estimates are in constant dollars, do not assume any inflationary factors (traditionally higher in health care than in the rest of the economy), and assume that these children encounter no diabetes-related complications before age 21 years.

Texas youth with diabetes in 2025 will incur $15 billion in medical costs over their lifetime—an astonishing figure. If we arrive at 2025 without any changes, we will have failed the youth and coming generations and left taxpayers with an unprecedented economic burden. The first way to mitigate this outcome is through research to find effective ways to prevent and control diabetes and to avoid or delay complications.

Diabetes Research in Texas

Talented Researchers Hampered by Limited Funding

Texas has an internationally recognized cadre of capable pediatric diabetes investigators and clinicians, but the state's research efforts are grossly underfunded for the size of the population at risk of or with diabetes. Texas institutions received just six percent of all funds granted for diabetes research in 2002 by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Similarly, for fiscal years 1998-2002, just six percent of all grant funds awarded by the American Diabetes Association came to researchers in Texas. *More significantly, less than 10 percent of the research awards for diabetes were for studies specifically relating to children and youth*.

Diabetes in children and the escalating risk of type 2 diabetes in particular is a significant problem in both urban and rural communities of Texas. Opportunities for research exist not only in the areas of Houston, Dallas/Fort Worth, and San Antonio, but also in Corpus Christi, Amarillo, El Paso, and the Rio Grande Valley. All of these centers need research funding. Important work being conducted throughout the state related to children with diabetes includes:

1) environmental and nutritional factors that may trigger events leading to diabetes,
2) birth pattern differences,
3) cellular and mitochrondrial changes,
4) the roles of psychiatric disorders,
5) regulation of glucose metabolism in children, and
6) clinical trials to test treatments and lifestyle intervention.

The existing talent within Texas medical institutions provides a foundation for success in implementing coordinated pediatric diabetes research statewide. The strengths of Texas' public and private research institutions include clinical and epidemiological investigations, genetic studies, and the studies of insulin production, regulation, and function. Texas also has experts focusing on complications of diabetes, including cardiovascular disease, nephropathy (kidney disease), and neuropathy (nerve damage). However, to date the great majority of this research has addressed diabetes in adults.

Over the past year, scientists and clinicians in Texas pediatric centers have taken the initiative to collaborate on pediatric diabetes research efforts. These centers include the University of Texas Health Science Center, the University of Texas Medical Branch, and Baylor College of Medicine in the Houston area; Texas A&M University/Driscoll Children's Hospital at Corpus Christi, The University of Texas Health Science Center in San Antonio, and Valley Pediatric Associates in Brownsville. This consortium sees more than 500 children with newly diagnosed cases each year, including more than 250 youth with new onset type 2 and 300 children with new onset type 1 diabetes.

This informal group offers an incubator to pilot a research project. A key collaboration is already established with the University of Texas School of Public Health that has long-standing programs studying the epidemiology of diabetes in Texas and the genetic basis for the disease within specific populations.

Texas Academic Institutions

Funding for diabetes research can come from a variety of entities. Most of the diabetes studies within Texas academic institutions are conducted under the auspices of the National Institutes of Health (NIH). Non-profit groups such as the JDRF and the ADA raise funds to support basic scientific research. Private foundations and pharmaceutical companies fund specific projects such as clinical trials and product testing.

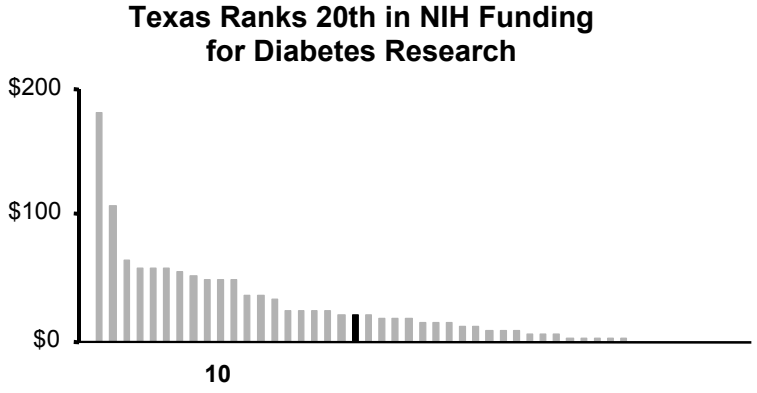
A simple analysis of grants awarded for diabetes research includes funding directly related to the disease, not its complications. Any attempt to categorize diabetes funding underestimates the actual funding because some grants are dedicated to affected organ systems, including cardiovascular, renal, digestive, neurological, reproductive, and ophthalmologic.

The table below depicts known research activity in institutions that can be directly attributed to diabetes and their funding sources as identified through a simple survey.

Institution	*Total #**	*NIH / CDC*	*NASA***	*JDRF*	*ADA*
Baylor College of Medicine, Houston	38	8		6	3
MD Anderson, Houston	1			1	
Texas A & M University, McAllen	1			1	
Texas Tech University, Lubbock/El Paso	9	1			
University of North Texas, Fort Worth	2				2
University of Texas, Austin	2	2			
University of Texas Health Science Center, Houston	18	13	2		
University of Texas Health Science Center, San Antonio	58	39		2	4
University of Texas Medical Branch, Galveston	51	--	--	--	1
The University of Texas Southwestern Medical Center, Dallas	13	8		2	5
Total	193	71	2	12	8

**The total includes other, unspecified funding sources.*
***National Aeronautics and Space Administration*

However, Texas, receiving only $23.25 equivalent per adult with diabetes, ranks 20th in NIH funding when compared to other states on a per-person-with-diabetes basis. The highest funded areas per capita are the District of Columbia, the home of NIH, ($490), followed by Massachusetts ($180) and Colorado ($106).



In the course of its investigation, the Committee was unable to quantify the research being conducted in the private sector. Significant research and development related to diabetes are occurring in Dallas, Houston, and San Antonio. But these proprietary ventures restrict the release of information related to ongoing projects, so the nature or extent of these activities could not be readily obtained. In general, such private sector research and development (biotech) companies are established in areas in which substantial basic and clinical research is being conducted. Such companies frequently, in fact, are spun off from such activities.

Texas has a quality core of excellent scientists, so how can we catapult this state into being among the top-funded states in the country?

Texas Pediatric Research Advisory Committee Recommendations

Research endeavors were categorized into three areas: etiology (causes), treatment, and prevention. Recognizing and overcoming the limitations in each of these areas are critical to conquering pediatric diabetes.

> ***Etiology—***Except for broad statements regarding risk factors, it is not possible to state what causes an individual child or youth to develop diabetes or specific complications.
> ***Treatment—***The goal of diabetes treatment is to maintain blood glucose levels as normal as possible. Models for treatment are not standardized, and most models are based on experience with adults.
> ***Prevention—***Prevention efforts must address both primary prevention (delay of diabetes onset) and secondary prevention (delay of complications). Without developing and implementing effective prevention, the State of Texas cannot slow the projected increase of new cases and their impact.

The Committee considered an extensive array of research issues within these three categories. Appendix II includes a detailed description of this work. Among the projects considered were many important endeavors designed to further our understanding of the causes, treatment, and prevention of pediatric diabetes. Rather than lend its support to any or all of these specific research endeavors, however, the Committee concluded that Texas faces a more fundamental requirement.

The Committee identified the acute lack of standardized data—including patient/family medical and demographic data and biological specimens—as the most pressing requirement to support essential scientific inquiry within the Texas pediatric diabetes research community. This need is underscored by the differences between projected new cases in coming years based on available studies with census-based population projections and the anecdotal reports of new cases from primary and specialty physicians. This conclusion led to two recommendations that Committee members believe will serve as the underpinning for a coordinated approach to the state's pediatric diabetes research efforts to understand and prevent diabetes in the children of Texas today and in the foreseeable future.

The Texas Pediatric Research Advisory Committee proposes that:

1) **diabetes mellitus diagnosed before the age of 21 years be a reportable disease to the Texas Department of Health and**
2) **the Texas Legislature support the establishment of a Texas Pediatric Diabetes Research Resource (TPDRR).**

Instituting these strategic elements in Texas would facilitate important developments in etiology, treatment, and prevention. Building a substantial research core also would encourage greater cooperation among various academic institutions and lead to greater leveraging of state funds to increase federal and private matching dollars—with the ultimate goal of reducing the impact of diabetes on Texas children and their families.

Make Pediatric Diabetes a Reportable Disease
Crucial to a Texas diabetes information database is that pediatric diabetes be designated as a disease reportable to the Texas Department of Health. This reporting procedure would provide a practical and effective means to assure a more representative picture of youth affected by diabetes within the state and a measure from which to accurately estimate incidence and trends in Texas. A population-based approach supplements local studies and reports and helps policymakers identify trends and high-need areas.

By limiting reporting to newly diagnosed pediatric cases, the state's medical practitioners can anticipate a modest requirement for information dispersed among an estimated 500 to 1,000 patients each year. The potential long-term research benefit to health care providers—especially pediatric diabetes specialists who treat the majority of pediatric type 1 diabetes cases and many type 2 cases—offsets this proposed requirement.

Establish the Texas Pediatric Diabetes Research Resource (TPDRR)
A pediatric diabetes research resource would use existing facilities and agencies to gather and coordinate biological and scientific material for use by investigators in Texas. The information available through the TPDRR would include:

1) historical, demographic, and medical financial data, which would be coded to protect confidentiality, and
2) stored DNA and plasma from children with newly diagnosed diabetes and their family members who volunteer to provide these samples.

The data and resources held by the Resource would support pediatric diabetes investigators across the state employing a wide variety of scientific approaches, including basic research. The TPDRR would be available to independently funded pediatric diabetes investigators, thus allowing the state to leverage new funding from federal and private sources for medical research programs within Texas. Confidentially managed information from the Resource also could be used to facilitate recruitment of volunteer subjects for studies related to diabetes.

Criteria for Recommendations
The proposed Resource meets the criteria set by the Advisory Committee to:

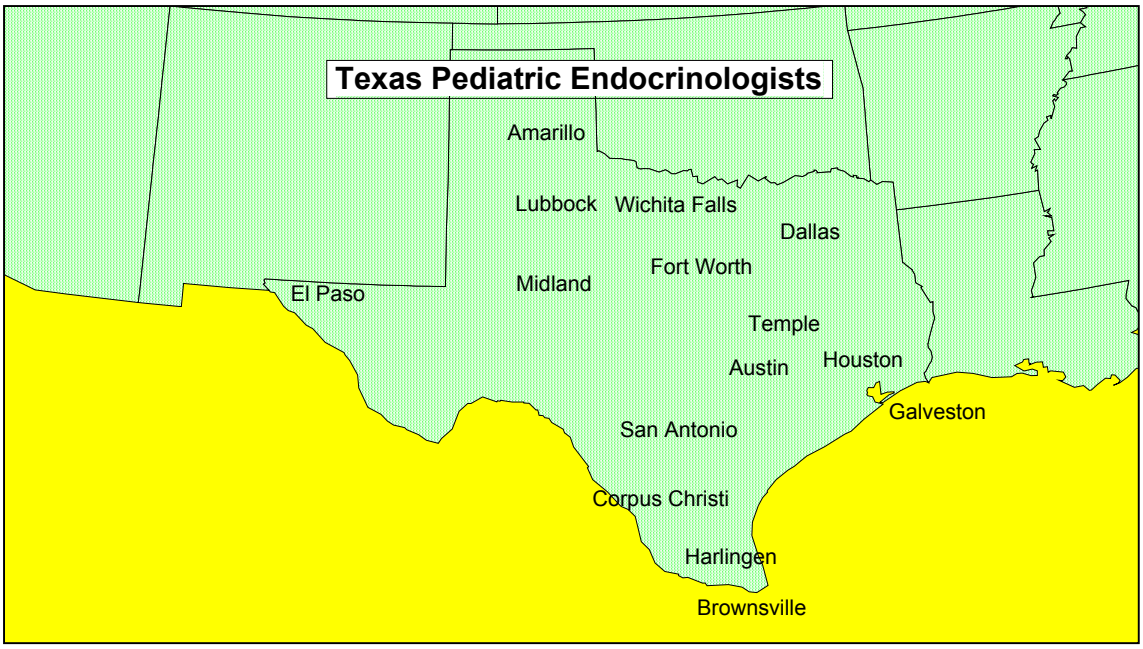
1) benefit children with or at risk of diabetes and their families throughout the state,
2) be unique to the State of Texas,
3) be based on state-of-the-art science that will have validity over time,
4) serve as a significant multiplier in attracting new federal and private research support,
5) provide demonstrable progress in medical and clinical research through measurable outcomes, and
6) contribute to reducing the economic burden to the state over time.

Phase I: Registry and Samples

The number of children with new onset diabetes is projected at only 500 to 1,000 per year. Health care providers would report all newly diagnosed cases, but patient participation in any detailed data or blood sample collection would be voluntary. The process would include strict requirements for written informed consent of a guardian (in the case of someone less than 18 years old) or patient (in the case of someone over 18 years old) and assent of a minor over age seven. Children (up to age 18 years) and adult patients (18-21 years) identified with diabetes in Texas, along with their immediate family members, would be invited to participate within four months of diagnosis.

Key activities would be to obtain a complete medical and family history of the individual diagnosed with diabetes and his/her immediate family members (i.e., parents, grandparents, and siblings). Participants would be asked to provide a blood specimen that would be processed for DNA and plasma samples. Clinical, demographic, and economic (cost-of-care) data would be entered into a centralized database. Confidential information about patients would be carefully protected according to federal guidelines and statutes. The Texas Department of Health (TDH) has experience with registry development and management, e.g., cancer registry and birth defects registry.

Due to the density of populations in metropolitan areas, it can be anticipated that the majority of participants would be found in the state's larger population hubs. The concentration of pediatric endocrinology practices in these areas also would favorably affect clinicians' ability to enlist patients and their family members. However, a goal of widespread implementation and participation of children throughout Texas is critical to ensure that the data captured are representative of the entire state, embracing rural and unincorporated areas from the Panhandle to the Lower Rio Grande Valley and from El Paso to Orange. The pediatric endocrinologists connected to the TDH newborn screening program can be identified and engaged.



Source: TDH Newborn Screening
September 2002

As the number of children identified and the stockpile of information and research materials grow, the value of the TPDRR will increase proportionately. Given the possibility that 5,000 sets of family-linked samples could exist within five years, access to the Resource will be highly sought. Rules governing access to materials (DNA and plasma) collected within the Resource would safeguard and provide for judicious allocation of this limited reserve of assets.

The Advisory Committee proposes that access to these biological resources be issued after approval by a TPDRR review committee composed of established diabetes investigators from across Texas. The review committee would consider only those research proposals that also have been submitted for peer review at the national level (e.g., NIH, CDC, JDRF, ADA, NSF, USDA). Approval for use of TPDRR would be contingent on national funding. Requestors would be required to build users' costs for materials provided by the Resource within their proposed budgets. Thus the Resource could recover costs over time to become financially self-supporting.

Building the requirement for a successfully funded, nationally peer-reviewed proposal into the approval process will:

1) assure that high-quality scientists focused on pediatric diabetes will have access;
2) increase the potential for federal, private, and non-profit funding for pediatric diabetes research within the state;
3) stimulate new interest and research investigation on pediatric diabetes from multidisciplinary areas of medical, economic, and sociological science; and
4) provide a mechanism for the continued, long-term support of the Resource, independent of state funding.

Examples of the potential for wide applicability of this Resource are provided in Appendix III. An assessment of how well the Texas Pediatric Diabetes Research Resource meets the Committee's criteria for recommendations is provided in Appendix IV.

Thus, this Resource will serve as a multiplier of any state funds invested and will create new knowledge about pediatric diabetes in general and specifically about pediatric diabetes within Texas.

Implementation

A number of pediatric diabetes centers have begun collaborating over the past year in joint research efforts addressing type 1 and type 2 diabetes in children. With the engagement of researchers from many of the state's academic institutions, this research consortium would be an ideal group with which to pilot the resource concept. Once a working model is established and procedures defined, the pilot group would recruit other centers with pediatric endocrinologists, pediatricians, family practitioners, and other professionals serving children with diabetes.

Proposed Funding for Texas Pediatric Diabetes Research Resource

A formal *proforma* has not been prepared. However, several considerations should be made regarding start up and continued funding. The Advisory Committee is cautious to propose a line item expenditure in the current climate of budgetary constraints and competing priorities—one being the care of many of these youth under Medicaid or state Children's Health Insurance Program (CHIP). However, the state must initiate this adjunct in order to reduce the negative human impact of this disease, as well as its direct and indirect costs to the state. If timely action is not taken, taxpayers and private health insurers will unwittingly spend literally billions of dollars on this condition.

A bold initiative is required to meet the challenges of pediatric diabetes. The first biennial budget should be sufficient to begin addressing all three arms of the research agenda: etiology (causes), treatment, and prevention. Florida and Oregon each have a new and unique state-sponsored program. Florida, in partnership with the American Diabetes Association, endowed newborn screening with $20 million ($10 million from the ADA and $10 million from the State of Florida). Monies generated from the investment of these funds are the capital to be used for operating the program. A similar approach in Texas would offer several advantages:

1) it is a one-time passage by the state Legislature;
2) there is no ongoing line item in the budget susceptible to cuts and/or modifications, thus assuring the ongoing existence of the program;
3) it establishes a partnership with a national funding organization whose primary mission is diabetes, such as the NIH, ADA, and/or the JDRF, which recently partnered in a program to increase the number of pediatric diabetologists in the United States; and
4) it would shelter the Resource from those who might be tempted to tap into these funds for other interests.

The Oregon legislature (2001 Regular Session) authorized the establishment of a statewide database for the collection of information on type 1 and type 2 diabetes occurring in children. The database supports surveillance (incidence and prevalence), scientific research studies, and decisions about public resources allocation. Reporting obligations are assigned to physicians and schools.

Time Line

In order to establish a functional Texas Pediatric Diabetes Research Resource and demonstrate the utility of the project, a seven-year time frame is outlined to depict the initiation and development. Within that time, the Legislature can examine the contribution of the pediatric diabetes research endeavors fostered, developed, and supported, as well as the economic value to the Texas economy.

Preliminary Time Line

Year	*Activity*
One	Identify: Director Coordinating committee members Scientific advisory committee members Establish policies and procedures Engage collaborating centers
Two	Initiate sample collection in pediatric endocrinology collaborating centers
Three	Expand sample collection to all pediatric endocrinology practices
Four	Statewide sample collection Review new investigator proposals and annual progress reports
Five	Statewide sample collection Review new investigator proposals and annual progress reports Initiate basic science core
Six	Statewide sample collection Prepare report to the Legislature
Seven	Statewide sample collection Review new investigator proposals and annual progress reports Submit report to the Legislature

Conclusion

The members of the Texas Pediatric Diabetes Research Advisory Committee spent many hours studying the personal and economic impact of pediatric diabetes on individuals and the state and evaluating the resources that are needed to effectively address this issue. The recommendations contained in this report are based on thoughtful deliberations and are unanimously supported by the Committee members.

This report was prepared with assistance from the staff of the Diabetes Program, Texas Department of Health. More information on the Committee's activities is available from:

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Codicil 1. Funding for Clinical and Basic Science

By year 5 of the Texas Pediatric Diabetes Research Resource, the Committee proposes the establishment of a component that would allocate funds for investigations of the causes, complications, and prevention of diabetes in children at a fundamental (basic science) or clinical level. Funding research aimed at discoveries that come from basic science provide leverage to securing other funds, e.g., NIH and private entities. Similar to the procedure described above for accessing data and/or samples, an investigator would submit a proposal from a Texas public or private institution to the scientific review Committee. They would consider a proposal conditional upon submission to a national funding agency.

The Committee proposes that a funding strategy be created through the Texas Higher Education Coordinating Board for the Advance Research Program (ARP) and Advance Technology Program (ATP).

A modest budget of $20 million every two years ($10 million a year) is proposed to fund the Clinical and Basic Science Core from the Texas Higher Education Coordinating Board. The Committee estimates that if Texas funds these research efforts, the state will receive more money (through an increase in federal and private funding) than the amount proposed to be invested. This mechanism ensures that the best scientists and best scientific approaches are funded. With this support, effective prevention and cure will come sooner for children with diabetes and their families, thereby saving millions of dollars annually for the State of Texas.

Codicil 2: Basic Services

In addition to support for long-term research initiatives, the Texas Pediatric Diabetes Research Advisory Committee recommends that the Texas Department of Health, related institutions, and the Legislature support the following actions for near-term benefit to children with type 1 or type 2 diabetes or at risk of developing diabetes and their families:

1) require all third party payers, including Medicaid, CHIP, and private insurers, to provide adequate reimbursement for all pediatric diabetes-related services, including education and preventive services;
2) promote positive lifestyles by increasing the hours of the school year committed to physical activity for all children (consistent with recommendations from the American Academy of Pediatrics);
3) limit access to foods of minimal nutritional value in vending machines, food sales, and fundraisers in schools and other state-supported institutions;
4) implement health education focused on healthy lifestyle, including basic nutrition practices and daily, safe, moderate-to-vigorous physical activity;
5) encourage the Texas Department of Health to develop simple, culturally relevant, easily readable materials related to healthy lifestyle for distribution to primary care providers and public health clinics throughout the state;

6) offer incentives for communities and real estate developers to develop safe venues for physical activities (sidewalks, parks) and/or increase access to such venues (school sports fields open after hours);
7) support research on the efficacy of the above strategies in decreasing risk factors and/or improving health outcomes for children with diabetes in Texas; and
8) take steps to increase the number of pediatric endocrinologists in Texas, which currently has a total of 32 such practitioners

Appendix I: Criteria for Recommendations

In determining their final recommendations, the Committee compared a wide variety of options to develop a state-supported research agenda for children with or at risk of diabetes to the following criteria:

1) The program should potentially benefit children with or at risk of diabetes and their families throughout the state.
2) The program should be unique to the State of Texas.
3) Methods should be based on state-of-the-art science that will have validity over time.
4) The program(s) supported by state or private funds should serve as a significant multiplier in attracting new federal and private research support.
5) The program(s) should provide demonstrable progress in medical and clinical research through measurable outcomes.
6) The program(s) should contribute to reducing the economic burden to the state over time.

Appendix II: Potential Areas of Research

Never before have more individuals been involved worldwide in the study of diabetes nor has more funding existed for diabetes research. Nearly every avenue is being explored to improve our understanding of the pathophysiology, treatment, and prevention of type 1 and type 2 diabetes. Few of these activities, however, are directed specifically to children.

Outlined below are research aspects being pursued by scientists in academic centers and/or in private industry. The descriptions that follow discuss the Pediatric Diabetes Research Advisory Committee's consideration of the feasibility of each item as part of a coordinated statewide research effort.

Ultimately, members concluded that the pressing need for standardized data—including family data and biological specimens sufficient to permit essential scientific inquiry—was the most basic need, underlying all other issues considered.

1. ETIOLOGY (causes)
    a) Islet and cellular biology
        (1) Cause of beta-cell failure in type 2 diabetes
        (2) Immunologic trigger for type 1 diabetes
    b) Pathophysiology (role of beta-cell destruction)
    c) Genetics (phenotype and genotype)
    d) Epidemiology

2. TREATMENT
    a) Pharmaceutical agents
        (1) Insulin, insulin sensitizers, beta-cell stimulators for insulin release, appetite control
    b) Improved treatment and control devices
        (1) Continuous glucose monitoring
        (2) Implantable insulin pumps
    c) Behaviors: treatment adherence to control complications
    d) Insulin-secreting beta-cell replacement
        (1) Drugs that stimulate differentiation of existing pancreatic progenitor cells (stem cells in pancreas)
    e) Gene therapy

3. PREVENTION
    a) Obesity prevention
    b) Behavioral change: physical activity and nutrition
    c) Services to children

Assessment of Potential for Texas Research

1. ETIOLOGY

1.a. Islet and Cellular Biology

A number of Texas scientists are involved in research to delineate the molecular biology and control of the isle of Langerhans, which contain the insulin secreting β-cells. In addition, these pursuits may lead to the discovery of the trigger that results in the autoimmune response that destroys the β-cells in people with type 1 diabetes or causes the early death of the β-cells in people with type 2 diabetes. Great progress has been made in this area over the past decade, outside of the development of β-cells from stem cells. These endeavors are largely directed at the basic science of the islet in which lies the foundation for developing a product to improve the lives and future of children with diabetes. These scientists will uncover the causes of both type 1 and type 2 diabetes which, in turn, will help others design the approaches to cure, control, and even prevent this complex condition.

1.b. Pathophysiology (role of beta-cell destruction)

An aggressive effort is underway to determine the relationship between chronic poor metabolic control (hyperglycemia) and known complications of diabetes. Genetics clearly play some role in the likelihood of developing complications. Other factors include maintaining blood pressure and serum lipids and blood sugar concentration in a near-normal range**.** Of all of these areas, maintaining the blood sugar in a near-normal range is the primary preventive strategy to reduce the risks for renal, neurological, vascular, cardiac, and eye disease. Clinical trials have been carried out in a limited way and only in the adult population. The trials address some, but not all, complications and some, but not all, co-morbid conditions, e.g., high blood pressure. A number of pediatric centers in the state have developed a treatment consortium and applied for NIH funds in response to new requests for applications looking at the etiology of diabetes and the management of type 2 diabetes in children.

1.c. Genetics

It has been known for decades that diabetes is a complex multi-gene disorder with environmental and behavioral factors superimposed. With the near completion of the sequencing of the human genome, we now have a road map to many little-known genes that might create increased susceptibility to diabetes—whether type 1 or type 2. This roadmap was unthinkable even 10 years ago. Marker genes for the autoimmune response exist (HLA and DR genes) for type 1 as well as a number of genes involved with glucose/insulin signaling. DNA sequencers and a number of cloning and sequencing strategies now make it possible to sequence completely a wide variety of genes to evaluate the impact of a variety of combinations of specific gene alleles.

These new and powerful techniques, particularly if combined with both clinical and physiological data from subjects and their immediate family members, could be used to define individuals at risk and new gene associations, improve therapeutic targeting, and potentially prevent diabetes. For the first time, genotype/phenotype correlations in a defined patient population could be provided. No resource exists today that can provide

this information in a single population, let alone in such a multi-ethnic population as exists in Texas.

It may be unrealistic for the State of Texas to fund such a sequencing facility, despite decreasing costs. However, the voluntary, systematic collection of patient and family plasma and DNA at the time of diagnosis in a defined patient population over a period of time would be an extraordinarily unique and important research resource. This resource would be of value now and for years to come. And it could only be established legislatively, not through investigator-initiated proposals.

1. d. Epidemiology

To understand fully the impact of diabetes on Texas' children, on the state, and on private resources, it is invaluable to know the incidence (number of new cases per year) and prevalence (current total number of cases) of diabetes in infants, children, and adolescents (under 21 years of age). From a number of pediatric endocrinology practices throughout the state, we gain better understanding of both of these factors. However, a substantial number of children with diabetes are not seen by pediatric endocrinologists (diabetologists).

Thus, while we may know some number of children with diabetes, we cannot know the total number since this is not a disease that is reported to the Texas Department of Health or the CDC. Within metropolitan areas, where pediatricians and family practitioners are more likely to refer patients to a pediatric endocrinologist, we have an opportunity to carefully define the incidence and prevalence of diabetes and extrapolate to the total numbers of children by ethnicity throughout the state. We need information sources in rural and isolated settings, such as community health centers, school nurses, and institutions with programs directed to rural health care, to complete the picture. Obtaining valid epidemiological data is a costly and time-consuming process that provides a "snapshot" of limited temporal, but great historical, interest.

A number of centers in South Texas have begun to collaborate on several recent grants. These centers may provide the catalyst for epidemiological studies. This would be a potential area for legislative support since more accurate data would provide the state and the Texas Health and Human Services Commission better estimates of the cost to Medicaid, CHIP, and private payers responsible for children with diabetes.

This Committee recognized previous efforts to establish a voluntary registry of names/addresses of people in South Texas with self-reported diabetes, which serves as a mailing list for those people or their relatives (if they are deceased). Such a collection does not replace the important medical clinic-based registry of clients, which is a critical component to track and improve the delivery of services consistent with the standards of care for diabetes and to assess the progress in reaching treatment targets.

Finally, the Committee recognized current legislative attention and support to raise awareness of the risks of developing diabetes in later life by counting school-age children with *acanthosis nigricans*, a skin marker for high insulin levels, usually found in people who are obese. With this beginning endeavor, Texas is ready to move forward

with the medical and scientific communities, using a standardized approach to recognize and account for diabetes and its risk among youth.

2. TREATMENT:

2. a. Pharmaceutical Agents

The development of new pharmaceutical agents is the responsibility of privately funded companies. It is expensive and requires a large number of potential candidate drugs in development to bring a single agent to clinical trials. However, the profit potential for effective agents such as insulin sensitizers (thiazolidinediones) is enormous. A number of pharmaceutical companies throughout the world are frantically attempting to develop drugs to alter the action of insulin, to affect appetite or increase energy expenditure (all for weight reduction), to increase insulin secretion from faltering beta cells (which make insulin), or to stimulate "pancreatic specific" progenitor cells to develop into new insulin secreting β-cells.

2. b. Improved Treatment and Control Devices

A variety of insulin pumps have improved the quality of life for some children with type 1 diabetes. These devices have not been used widely in children with type 2 diabetes because of the increased weight gain seen in children treated with insulin as mono-therapy. The development of an insulin pump linked with a continuous glucose monitor, however, would dramatically change management of both type 1 and type 2 diabetes in children. Whole industries with significant venture capital are pursuing the development of the continuous glucose monitor with the hope of integrating this device with an insulin pump. If a reliable and affordable device that is acceptable to patients were developed, the management of diabetes among youth would be revolutionized. Engineers have been attempting to develop such a device since the early 1980s with the implementation of the artificial beta cell or Biostator® for research purposes. Only two devices are currently approved by the FDA, and both have potential significant problems. There are companies in Texas that have initiated work on such glucose sensors and have support from the NIH and/or American Diabetes Association (ADA). Some companies are exploring this area with funding from Juvenile Diabetes Research Foundation International (JDRF) and/or ADA.

These activities are appropriate for the private sector and offer the potential for profits, while providing employment opportunities for capable technicians and scientists prepared by Texas schools.

2. c. Behaviors: Treatment Adherence to Control Complications

The ultimate success of any patient with diabetes—at any age—includes:

- acceptance of their disease,
- knowledge and utilization of that knowledge to manage their diabetes, and
- motivation to perform requisite activities to maintain blood glucose within the normal range.

As a result of the landmark studies on controlling diabetes to minimize complications, we know that blood sugar control primarily determines the long-term micro- and macrovascular outcomes of this disease in both type 1 and type 2 diabetes.

Accomplishing ideal blood glucose control requires the acquisition of knowledge (insulin action and the impact of illness, physical activity, and diet on their blood sugar), skills (insulin injection, glucagon administration, self glucose monitoring), and modification of lifestyle.

Diabetes is unique in its management because the ultimate outcomes rest with the affected individual and his/her family. They must incorporate the requisite lifestyle changes into their daily routine, they must perform a multitude of disease-specific tasks multiple times each day, and they must integrate disease management into normal family and school life.

The primary roles of the diabetes care team are:

1) designing the medical and lifestyle program for the affected child,
2) helping the family cope with the daily stress of the disease,
3) educating the family and the patient about the disease in an age- and educationally appropriate manner,
4) empowering families to participate in diabetes management, and
5) assisting with diabetes care during concurrent illnesses.

Facilitating effective diabetes management requires frequent, intense contact between the health care team and families over a long period of time. Such contact may occur via face-to-face interactions (office visits for examinations and dietary education), telephone (handling an acute episode of hypoglycemia), fax or e-mail (reporting blood glucose levels to the health care team in order to obtain advice regarding optimal insulin therapy). With reference to the epidemic of pediatric diabetes sweeping the state, the issues of diabetes management are especially problematic because the most critical aspect of management involves lifestyle modification. This has proven extremely difficult to accomplish in both adults and children.

At present, the reimbursement from all third-party payers for services to children with diabetes is dramatically lower than the actual costs of delivering these services, and many of these services are not reimbursed at all. Many children in Texas do not have access to, or continuity of, diabetes care except for the generosity of the institutions whose talented staff see and care for these children. Without this care, affected children are destined to long-standing poor metabolic control as well as early onset and progression of the complications of diabetes (heart attacks, stroke, end-stage renal disease, new onset blindness, atherosclerosis, lower limb amputation). Diabetes cannot be denied its due: short-term failures of diabetes management include multiple hospitalizations for ketoacidosis and associated morbidities while long-term failures result in the panoply of complications outlined above.

2. d. Insulin-secreting Beta-cell Replacement

A variety of methods are being explored to replace the damaged insulin secretory capacity in individuals with diabetes. The transplantation of insulin-producing beta cells by both pancreas and islet cell techniques is an ongoing and successful method of accomplishing blood sugar control, which studies have shown to delay and decrease the severity of complications of diabetes. Most of these studies have been carried out in adults with type 1 diabetes, and none have been carried out in children. Partial (most

commonly a living donor) or whole pancreas (cadaver donor) transplants are limited by the problems of surgical complications, a skilled surgical and medical team, the requirement of immunosuppressive therapy for the life of the transplanted organ, and the severe limitation in the availability of these donated organs. These procedures have almost always been limited to adults who have developed the complication of renal failure. These patients usually will have a kidney(s) (renal) transplantation either before or at the same time as the pancreas transplant. Within Texas, the University of Texas Health Science Center of Houston, Baylor College of Medicine/Methodist Hospital, UTMB-Galveston, UTHSC-San Antonio, Baylor Medical Center-Dallas, and Texas A&M at Scott & White currently perform kidney-pancreas transplantations.

In the past several years, investigators have been able to purify human islets from cadaver pancreata and infuse them into the portal vein of the recipient's liver. This has been the proof of principle of something that has been known to be possible in rats since the early 1970s. Although an extremely promising technique, since risk of death for the patient is minimal, it is still limited by the experimental nature of the procedure, the immunosuppressive drugs that are required, and the limitation in donor pancreata as noted above. The procedure is rarely successful with the islets harvested from a single pancreas and generally requires two and occasionally three organs. However this research will pave the way for the introduction of β-cell derived from stem cell research.

2. e. Gene Therapy

In the coming 20 years, stem cell research potentially offers a "cure" in individuals with type 1 diabetes and dramatically may improve management and therapy of the type 2 diabetes. Embryonic or adult stem cells are pluripotent (no fixed development) and current research suggests that these cells in culture can be induced to develop into pure β-cell. If this is possible, unlimited numbers of human β-cells could be grown in the laboratory and infused in diabetics. The likely success of this approach is extremely high and scientists are extremely enthusiastic about their final outcome.

Another approach is to engineer cells to produce and secrete insulin in a glucose-sensitive manner. These cells then can be used for cell-based therapy. This route of research is currently ongoing and expected to succeed as well. The excitement for this line of experimental work is tempered only by recognizing the considerable costs associated with developing effective techniques and follow-up care, by the limited number of donor organs in light of the number of persons with type 1 diabetes who could benefit. The use of embryonic stems and its associated controversy can be avoided through the use of the progenitor cells in the pancreas that can be induced to develop into β-cells. However, at this time the necessary steps to complete this process are not yet fully understood. Although islet cell biologists have made a great deal of progress toward deciphering the keys to stimulating these cells to produce insulin the technology is not ready for use as human therapy. Therefore, the utilization of state funds in the pursuit of understanding the complex development of the islet cells appears to be an area of investigation that may not provide immediate benefit to our understanding of the cause of diabetes, its management, or its prevention in our children. Additionally, the NIH has made a substantial ongoing commitment to funding such basic science studies. It is certainly possible when this science has developed to the point that human therapies

become feasible, the State of Texas may want to support such studies to help make these therapies available to constituents with diabetes in a timely manner.

3. PREVENTION

3. a. Obesity Prevention

3. b. Behavioral Change: Physical Activity and Nutrition

(Primary Prevention)

Obesity—a major risk factor for type 2 diabetes—is increasing at alarming rates in all demographic groups, regardless of age, ethnicity, or socioeconomic level. Indeed, the national prevalence of obesity in children and adolescents almost doubled between 1982 and 1994, and there are many indications that this worrisome trend has accelerated since the last surveys were completed. No successful efforts to reduce the prevalence of obesity have yet been reported, and societal trends related to obesity prevention are extremely negative: increased caloric intake, decreased physical activity, and increased sedentary behaviors are well documented in all segments of US society. There is a desperate need to identify effective methods for lifestyle interventions that are sensitive to psychological development and the needs of children and youth. If risk management and/or prevention are successful, then children will benefit for many years and will have better chances of delaying, preventing, or controlling this disease.

3.b. Services to Children

(Secondary Prevention)

An important area of study is the determination of the cost effectiveness of various therapeutic interventions. This could be accomplished by comparing the costs of therapeutic interventions (in terms of health care work time and effort) to the costs of new therapies (whether it be islet transplantation or an new pharmaceutical agent). A statewide approach to research in diabetes in children would support this effort by providing the resource necessary to develop, execute, and coordinate studies to address specific interventional clinical trials and outcomes studies.

Appendix III: Wide Applicability of Research Resource

Demographic information could, in defined population areas, be used to determine the incidence of diabetes by ethnic and gender groups. Financial and cost data would be of inestimable value to health care planners from both the state and private sectors. This would in part contribute to an epidemiological aspect of this Resource. (Appendix II # 1.d)

Identification of unique family clusters of persons with diabetes would provide investigators the opportunity to ascertain the impact of the frequency of known diabetes genes alleles in type 1 and type 2 diabetes. This information may explain the onset of diabetes in the 6-month-old versus the 15-year-old. (Appendix II # 1.c.)

Using the DNA and the information obtained at the time of diagnosis would permit the screen for non-type 1 and non-type 2 diabetes (maturity onset diabetes of the young, or MODY) and would determine the frequency of these gene defects in the diabetic population. Use of family members' samples also would help determine whether heterozygote individuals are more susceptible to type 2 diabetes. (Appendix II # 1.c)

From unique family clusters of both type 1 and type 2 diabetes, researchers might identify genes that contribute to diabetes. (Appendix II # 1.c)

Matching selected clinical presentations with family histories and genetic information would help develop phenotype/genotype information that ultimately would be useful in identifying the etiology of diabetes as well as tailoring treatment to the individual patient's genotype. This could offer an opportunity to identify and pursue effective interventions to prevent complications. (Appendix II # 1.c)

The database also could help develop a patient or subject pool from which interventional clinical trials could be launched on a statewide basis. This would require collaboration across many centers, but permit more multidisciplinary trials. (Appendix II # 1.b., 2, and 3)

Appendix IV: How Recommendations Meet the Committee's Criteria

1) ***The program must potentially benefit children with or at risk of diabetes and their families throughout the state.***

The Texas Pediatric Diabetes Research Resource will address a broad cross-section of children with diabetes and their family members. The proposal will be directed exclusively at the pediatric population but may have tremendous potential for persons of all ages with diabetes. The Resource facilitates fundamental discoveries that could be rapidly applied to the care and management of children with diabetes.

2) ***The program should be unique to the State of Texas.***

Committee members are unaware of any other state or institution that has developed either of these potentially powerful resources. With its multi-ethnic society, Texas has a unique advantage with a Research Resource concept: the larger the patient population from all ethnic groups and regions, the more valuable the resource will become.

3) ***Methods should be based on state-of-the-art science that will have validity over time.***

No technique is more state-of-the-art than the gene sequences that might be generated as a part of this overall resource. These data will be coupled with well established techniques for the collection, storage, and retrieval of coded information and plasma samples on each child and their immediate family. Depending on the capture rate, these data also could be used as a disease registry and the origins of methods for doing both clinical and economic outcome studies. The confidential identification of unique types or phenotypes of diabetes across the state also would provide the opportunity for the Resource to sponsor or facilitate broad clinical trials in this patient population—something that only the NIH is undertaking at this time.

4) ***The program(s) supported by state or private funds should serve as a significant multiplier in attracting new federal and private research support.***

Likely entities include the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), United States Department of Agriculture (USDA), National Science Foundation (NSF), American Diabetes Association (ADA), Juvenile Diabetes Research Foundation International (JDRF) and Texas institutions. Reduced incidence, prevalence, or cost of diabetes are unlikely in the short term in the absence of a monumental discovery in diabetes. Initially, progress and success will be determined by the numbers and dollar amounts of grants brought into Texas.

5) ***The program(s) should provide demonstrable progress in medical and clinical research through measurable outcomes.***

New federal dollars that come to Texas as a result of this program will be tracked, as will the numbers of investigators and research publications supported by these proposals.

6) ***The program(s) should contribute to reducing the economic burden to the state over time.***

Over time, outcomes data on the incidence and cost of children with diabetes will be tracked.

Appendix V.
S.B. No. 1456

AN ACT
relating to the establishment of a pediatric diabetes research advisory committee in the Texas Department of Health.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
SECTION 1. (a) The commissioner of public health, in consultation with the Texas Diabetes Council, shall establish a pediatric diabetes research advisory committee.

(b) The pediatric diabetes research advisory committee is composed of the chairman of the Texas Diabetes Council or that person's designee and not more than 14 additional members appointed by the commissioner of public health in consultation with the Texas Diabetes Council as follows:

(1) one or more representatives of the Texas Department of Health;
(2) one or more representatives of the Juvenile Diabetes Research Foundation;
(3) one or more representatives of the American Diabetes Association;
(4) one or more research professionals from academic or biomedical research institutions in this state currently involved in diabetes research; and
(5) one or more representatives of the health care industry.

(c) The commissioner of public health shall select members of the pediatric diabetes research advisory committee based on the members' experience, expertise, or special interest in diabetes and:

(1) ophthalmology;
(2) pediatric endocrinology;
(3) child health and development;
(4) neuropathy;
(5) genetics;
(6) cardiology; or
(7) immunology.

(d) The commissioner of public health, with recommendations from the Texas Diabetes Council, shall select a member of the pediatric diabetes research advisory committee to serve as the presiding officer of the committee. The presiding officer may not be an officer or employee of the state.

(e) The pediatric diabetes research advisory committee shall:

(1) develop a plan to research pediatric diabetes and medical conditions associated with diabetes in this state;
(2) assess the resources and talent of institutions in this state as possible sites for research opportunities;
(3) analyze the impact of diabetes on the economy of this state and on the health of the residents of this state; and

(4) make recommendations to the Legislature and Governor concerning research programs in pediatric diabetes and funding alternatives for the programs.

(f) The pediatric diabetes research advisory committee shall meet at least four times as determined by the presiding officer. A professional facilitator with experience in strategic planning shall facilitate meetings of the committee.

(g) A member of the pediatric diabetes research advisory committee may not receive compensation for service on the committee but is entitled to reimbursement for reasonable and necessary travel expenses incurred by the member while conducting the business of the committee as provided by general law and the General Appropriations Act.

(h) Not later than December 1, 2002, the commissioner of public health shall submit a report prepared by the pediatric diabetes research advisory committee to the Governor, Lieutenant Governor, and Speaker of the House of Representatives regarding pediatric diabetes that comprehensively addresses the issues listed in Subsection (e) of this section.

SECTION 2. The commissioner of public health shall appoint members to the pediatric diabetes research advisory committee not later than the 90th day after the effective date of this Act.

SECTION 3. The pediatric diabetes research advisory committee is abolished January 1, 2003.

SECTION 4. This Act expires September 1, 2003.

SECTION 5. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2001.

_____ _____

President of the Senate Speaker of the House

I hereby certify that S.B. No. 1456 passed the Senate on April 5, 2001, by the following vote: Yeas-30, Nays-0, one present, not voting.

_____

Secretary of the Senate

I hereby certify that S.B. No. 1456 passed the House on May 8, 2001, by the following vote: Yeas-147, Nays-0, two present, not voting.

_____

Chief Clerk of the House

Approved:

_____ Date

_____ Governor

APPENDIX VI: Methodology for Projections

Projections for Type 1 Diabetes in Texans under 20:
Population Count, Incidence and Prevalence 1995-2025

All numbers in this report are based on population projections by the US Census Bureau for the years 1995-2025. The raw data can be found on the Web at:

http://www.census.gov/population/www/projections/stproj.html

Total Population

The race-specific population totals for each year were computed by simply summing the Census Bureau data from for each age (0-20).

Projection of Incident Type 1 Diabetes Cases

The number of incident cases by race was computed by multiplying the race-specific incidence rate and the race-specific population for each year. The incidence rates were 13 new cases per 100,000 people for Non-Hispanic Whites, 9 per 100,000 for Hispanics, and 11 per 100,000 for Blacks. It was assumed that the incidence rate was constant over time (no annual increase). Thus the increase in cases of type 1 diabetes is driven entirely by population growth. All incidence rates are taken from Table 3.4 on page 41 of Diabetes in America (NHW - Philadelphia, USA; Hispanics - Colorado, USA; Blacks - Philadelphia, USA), published by the National Diabetes Data Group of the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, MD, and accessible on the internet at http://www.niddk.nih.gov/health/diabetes/dia/contents.htm.

Projection of Prevalent Type 1 Diabetes Cases

The number of prevalent cases by race was computed by multiplying the prevalence rate and the race-specific total population for each year and adding this number to the number of incident cases. The prevalence rate used for these computations was 1.7 cases per 1000 people (Table 3.3, pg 39, Diabetes in America).

Projections for Type 2 Diabetes in Texans under 20:
Population Count, Incidence and Prevalence 1995-2025

All numbers for the total population in this report are based on population projections by the US Census Bureau for the years 1995-2025. The raw data can be found on the Web at:

http://www.census.gov/population/www/projections/stproj.html

Total Population

The race-specific population totals for each year were computed by simply summing the Census Bureau data from for each age (0-20).

Projection of Incident Type 2 Diabetes Cases

The number of incident cases by race was computed by multiplying the race-specific incidence rate and the race-specific population for each year. Several conservative assumptions were made. It was assumed that no incident cases would be observed in children 0-10 years of age and the incidence rate would be the same for children 11-20 years of age (no increased risk with age in this period). The initial rate beginning in 1995 was 6 new cases per 100,000 people for Non-Hispanic Whites, Hispanics, and Blacks. The incidence rate was increased 0.6 per 100,000 each year for Non-Hispanic Whites with a maximum incidence rate of 15 per 100,000. The incidence rate was increased 1.2 per 100,000 each year for Hispanics and Blacks with a maximum incidence rate of 30 per 100,000. These rates were chosen to match what appear to be current trends in changing rates and proportions of individuals diagnosed with either type 1 or type 2 diabetes aged 20 or younger.

Projection of Prevalent Type 2 Diabetes Cases

The number of prevalent cases by race was computed by multiplying the race-specific prevalence times the race-specific population for each year and adding the product to the number of incident cases. It was assumed that no incident or prevalent cases would be observed in children 0-10 years of age and the prevalence for children 11-20 years of age would be weighted linearly by age using the formula described below. In addition, the prevalence was increased each year by adding 70 percent of the previous year's incidence rate to the prevalence. Again this was a conservative estimate regarding the proportion of individuals diagnosed with disease that would remain in the population. The prevalence used for these computations was 4 cases per 1000 people (NHANES III).

The age weighting formula is:

Weighted Prevalence = (Prevalence) x [0.45 + 0.1 x (Age – 10)]

For example, in 1995 the prevalence for people aged 11 would be:

Weighted Prevalence = (4/1000)x[0.45 + 0.1x(11-10)]
= (4/1000)x(0.55)

and for people aged 20 the weighted rate would be:

Weighted Prevalence = (4/1000)x[0.45 + 0.1x(20-10)]
= (4/1000)x(1.55)

This weighting equation mathematically formalizes the notion that the prevalence should be higher in 20-year-old individuals than in 11-year-old individuals while maintaining the correct average incidence rate for the entire age range.

APPENDIX VII: Committee Members' *Curricula Vitae*

Maria C. Alen, MD, is an adjunct professor and clinical consultant with Texas A&M University Health Science Center - South Texas in McAllen, where she has lived for more than 20 years. She is a past chair of the Texas Diabetes Council and a member and leader of numerous local, state, national, and international diabetes organizations. Dr. Alen is dedicated to fighting diabetes at the research level, translating research into patient care, and supporting community-based programs, clinical research, and education. Dr. Alen obtained her medical degree from Universidad Nacional Autonoma de Mexico, Facultad de Medicina, in Mexico City and completed a residency in general surgery in Germany. She has conducted research in internal medicine and sports medicine and opened the first sports medicine laboratory and center at the Universidad Nacional Autonoma. She has practiced general surgery and was part of the faculty of the School of Medicine at Emory University in Atlanta. She also has practiced family psychiatry.

Barbara Anderson, PhD, is a licensed psychologist who has worked with children with diabetes and their families for 24 years in both research and clinical care. Dr. Anderson worked in the Diabetes Research and Training Center at Washington University in St. Louis and at the University of Michigan in Ann Arbor. She then worked at the Joslin Diabetes Center/Harvard Medical School in Boston for l5 years. Dr. Anderson recently re-located to Houston, where she is Associate Professor in Pediatrics at Baylor College of Medicine. Dr. Anderson has published extensively in professional and consumer journals on the psychosocial development of children with diabetes. She has a special interest in translating diabetes research findings into practical interventions that can be implemented in the pediatric health care system to support families and youth with diabetes.

J. Cornelius Brown, CHE, is president and chief executive officer at Dallas Southwest Medical Center in Dallas, where he is responsible for all financial and operational activities for this community-based hospital. He is an accomplished senior executive with over 25 years experience in the healthcare industry, including positions as assistant hospital administrator, chief operating officer, hospital administrator, health care consultant, and regional health care manager. He also is a former Air Force officer whose military career was primarily in health services administration. Before accepting his position at Dallas Southwest, Mr. Brown was the senior vice president for medical operations and corporate administration for a privately held company in Houston. Mr. Brown serves on the board of the University of North Texas Health Science Center Osteopathic Medicine Post Graduate Training Institute and is a member of numerous professional health care management organizations.

Daniel E. Hale, MD, is a tenured Professor of Pediatrics at the University of Texas Health Science Center in San Antonio, Chief of Pediatric Endocrinology and Diabetes, and Director of the Children's Center at the Texas Diabetes Institute. Dr. Hale earned his BS at Texas A&M University, and his MD at the University of Texas Medical School in Houston. He completed his pediatric residency at the Medical University of South Carolina, Charleston. His pediatric endocrinology and diabetes fellowship was conducted

at the Children's Hospital of Philadelphia and the University of Pennsylvania. He was on the faculty at the University of Pennsylvania and the Children's Hospital of Philadelphia from 1983 until he moved to San Antonio in 1994. He has authored more than 80 peer-reviewed articles concerning diabetes, fatty acid metabolisms, chromosomal defects, and other topics. He is a member of the Texas Newborn Screening Advisory Panel, the Lawson Wilkins Pediatric Endocrine Society, and the Society for Pediatric Research. He continues to participate in a wide range of pediatric clinical trials. He currently holds 2 National Institutes of Health diabetes-related grants. He will be the principal investigator for San Antonio for the NIH-sponsored pediatric treatment trial for type 2 diabetes – one of 12 centers in the United States.

Judith L. Haley, Houston, is an active community volunteer and diabetes advocate. In addition to being a member of the Texas Diabetes Council, she has served in leadership positions for the Juvenile Diabetes Foundation at the local and national levels. Two of her three children have diabetes. A graduate of the University of Houston, Mrs. Haley has worked as a representative for a pharmacy, a special events coordinator, and as assistant to the president of a local business.

Craig Hanis, PhD, is a professor of human genetics and epidemiology at the University of Texas Health Science Center at Houston School of Public Health. For more than two decades he has been investigating the epidemiology and genetics of type 2 diabetes among Mexican Americans. This work has centered in Starr County, Texas, which has the highest diabetes-specific mortality of any county in Texas. His studies were among the first to document the increased burden of diabetes among Mexican Americans and, most recently, led to the first identification of a gene for the common form of type 2 diabetes.

Morey W. Haymond, MD, is a graduate from the Washington University School of Medicine. Upon graduation he did his internship, residency, and pediatric endocrinology subspecialty fellowship training at Washington University School of Medicine in St. Louis Children's Hospital. Following five years on the faculty at Washington University School of Medicine, Dr. Haymond moved to the Endocrine Research Section of the Mayo Clinic in Rochester, Minnesota, where he advanced to the rank of Professor of Pediatrics. In 1990, Dr. Haymond became medical director of the Nemours Children's Clinic in Jacksonville, Florida, and vice chair for the Department of Pediatrics, University of Florida (Gainesville). In 1996, Dr. Haymond moved to Baylor College of Medicine, where he became vice chair for research and helped a number of research and clinical educational programs. He now serves as chief of pediatric endocrinology and metabolism and program director for the Clinical Scientist Training Program at Baylor. In 1999, he became medical director of the Pediatric Diabetes Care Center.

Stephen M. Katz, MD, is associate professor of surgery at the University of Texas Medical School Houston, Division of Immunology and Organ Transplantation, and medical director for the proposed Clinical Islet Transplant Program at UT-Houston. He is a member of several professional societies including the Transplantation Society, the American Society of Transplantation, the American Society of Transplant Surgeons (member, Cell Transplant Committee), the Cell Transplant Society, and the Immunology

of Diabetes Society. He is president-elect of the Texas Transplantation Society and associate medical director for the LifeGift Organ Procurement Organization. Dr. Katz is board certified in general surgery and critical care medicine. He has received funding from NASA and the Texas Advanced Technology Program to support his research in experimental pancreatic islet transplantation. His clinical interests include pancreas and kidney transplantation and laparoscopic donor nephrectomies. Dr. Katz is a graduate (?) of the University of Texas at Austin and Baylor College of Medicine.

Stephen W. Ponder, MD, CDE, is professor of pediatrics and director of the Children's Diabetes and Endocrine Center of South Texas at Driscoll Children's Hospital in Corpus Christi. He holds dual academic appointments with the Texas A&M University School of Medicine and the University of Texas Medical Branch, Galveston. His professional interest is in the area of diabetes mellitus in children and adolescents. Dr. Ponder is at the center of the emerging epidemic of type 2 diabetes (T2DM) and the metabolic syndrome (MS) in children. Recently, he collaborated with the International Diabetes Center to develop new clinical guidelines for management of T2DM and MS. He has served on numerous local, state, and national committees and boards. With 37 years of personal experience with type 1 diabetes, managed with the insulin pump, Dr. Ponder's clinical focus is on helping children and their families cope with the daily challenges of diabetes care.

William J. Riley, MD, is vice president of medical education at Driscoll Children's Hospital, Corpus Christi. He is associated with Texas A&M University System Health Science Center as regional dean for the Coastal Bend, vice chairman and professor in the Department of Pediatrics, and adjunct associate professor in the Department of Epidemiology and Biostatistics in the School of Rural Public Health. He also is a clinical professor for the Department of Pediatrics, University of North Texas Health Science Center. He has held other academic appointments at Texas A&M University, the University of Texas Health Science Center at Houston, and the University of Florida. Dr. Riley also has held local, state, and national leadership positions in the American Diabetes Association and is a member of numerous medical professional societies. He is the recipient of grants for diabetes-related studies from the National Institutes of Health, Diabetes Action Research and Education Foundation, Juvenile Diabetes Foundation International, and several pharmaceutical companies. He is the author of a number of published abstracts, original articles, and book chapters.

Craig W. Spellman, PhD, DO, is associate professor of medicine, head of endocrinology, director of diabetes clinics, and assistant dean for graduate studies at the University of North Texas Health Science Center at Fort Worth. During 1972-1986, he conducted research on molecular mechanisms of T-Cell mediated immunity at the University of Utah School of Medicine, University of New Mexico School of Medicine, and the Los Alamos National Laboratories. Currently, Dr. Spellman has a large university-based clinical practice at UNTHSC and is involved in several areas of research. He participates in many diabetes-related clinical trials. His basic research focuses on lipid biochemistry of HDL metabolism and molecular mechanisms of PPAR-γ gene activation. His work in epidemiology, in conjunction with the School of Public Health, UNTHSC, focuses on type 2 diabetes in children. His professional goals include defining the

incidence and prevalence of pediatric type 2 diabetes and investigating emerging cardiovascular risk factors in these children.

Sharilyn K. Stanley, MD, is associate commissioner for disease control and prevention for the Texas Department of Health. In that role, she oversees six bureaus, including the Bureau of Chronic Disease and Tobacco Prevention, the organizational home for the Diabetes Program. After completing a fellowship in allergy and immunology, Dr. Stanley investigated the immunopathogenesis of HIV infection. She also demonstrated the impact of tetanus vaccination on HIV-infected patients. Dr. Stanley moved from the laboratory to become special advisor to the director, National Institute of Allergy and Infectious Diseases, where she coordinated the HIV/AIDS and tuberculosis programs and represented the Institute on multiple HHS agency panels. In this capacity, she served as executive secretary to the HHS/Kaiser Panel on Clinical Practices for HIV Infection and was the responsible author for the HHS Guidelines for the Use of Antiretroviral Therapy in HIV Infection, published in 1998. Returning to Texas, she accepted the position of chief of the Bureau of HIV and STD Prevention at TDH. Among her accomplishments in that role are the institution of HIV reporting by name; passage of legislation to support a public health response to Hepatitis C; and restructuring of HIV prevention planning and service delivery for Texas.

Ming-Jer Tsai, PhD, is a Charles C. Bell professor of molecular and cellular biology at Baylor College of Medicine, where he teaches and conducts research. He received his bachelor of science degree from National Taiwan University in 1966, and his PhD in 1971 in the lab of Dr. Richard S. Criddle at the University of California, Davis, where he worked on RNA polymerases in yeast mitochondria. Dr. Tsai then pursued postdoctoral research at the University of Texas, M.D. Anderson Cancer Center, studying transcriptional regulation during tumorigenesis under Dr. Grady F. Saunders. In 1973, he joined the faculty of Baylor College of Medicine. Dr. Tsai's research for many years involves regulation of gene expression at the transcriptional level, especially on the insulin gene regulation and mechanism of steroid hormone action. In the last few years, he has shifted his research emphasis to elucidate the roles of transcription factors, bHLH transcription factors and nuclear orphan receptors, in embryonic development; specifically, he studies their role in pancreas, brain, heart and vascular development. He also conducts research on the role of steroid receptor coactivators in prostate cancer.

Surendra K. Varma, MD, holds several appointments with Texas Tech University Health Sciences Center, School of Medicine, in Lubbock: distinguished professor and vice chairman of pediatrics, professor of physiology and health services research, and director of the pediatric residency program. Dr. Varma is a graduate of King George's Medical College, Lucknow, India, where he also was an intern. He was a postdoctoral fellow at Harvard Medical School and completed a residency in pediatrics at Massachusetts General Hospital, Boston. He is a fellow of the American College of Endocrinology. Dr. Varma served two terms as president of the Texas Affiliate of the American Diabetes Association and has held leadership positions with the Texas Medical Association and Texas Pediatric Society. He was instrumental in getting the Newborn Hypothyroid Screening law passed in Texas. Dr. Varma is the author of

numerous medical publications and has lectured on diabetes at conferences throughout the United States, as well as in India, Mexico, Canada, and England.

Kittie Wyne, MD, PhD, is an assistant professor in the Division of Endocrinology and Metabolism at the University of Texas Southwestern Medical Center at Dallas. Dr. Wyne earned her medical degree from the Pritzker School of Medicine at the University of Chicago and doctorate in pathology from the University of Chicago. She also holds a master's degree in human biology from the University of Chicago. After serving a residency in internal medicine at Baylor College of Medicine, Houston, she completed her fellowship in endocrinology, diabetes, and metabolism at the University of Texas Southwestern Medical Center, Dallas, where she subsequently joined the faculty. Dr. Wyne has published journal articles on her work in endocrinology, lipid metabolism, and diabetes treatment. She has received a Career Development Award from the Juvenile Diabetes Research Foundation International.