Diabetes Research and the Public Good: Federal Support for Research on Type 1 Diabetes

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I. Introduction and Executive Summary

Diabetes is one of the most common, life-threatening medical conditions in the United States today. Nearly 26 million Americans had diabetes in 2011, up from 24 million in 2007, according to the Centers for Disease Control and Prevention (CDC).[2] All told, more than 8 percent of all Americans have some form of the disease.

As alarming is the fact that the prevalence of diabetes is increasing faster than the population. From 2001 to 2009, type 1 diabetes (T1D) among youth increased 23 percent, and type 2 diabetes (T2D) among youth increased 21 percent.[3] Epidemiologists estimate that by 2020, nearly 12 percent of Americans or 39.2 million people will have diabetes, including 28.7 million diagnosed cases and 10.5 million undiagnosed cases.[4]

The impact of diabetes is enormous. According to the CDC, diabetes is the underlying cause of death of over 70,000 Americans a year and a contributor to an additional 160,000 deaths. People with diabetes are two-to-four times more likely than other people to die of heart disease. Diabetes is the leading cause of kidney failure, accounting for 44 percent of all new cases, and it is the leading cause of new cases of blindness in adults.[5]

The consequences of diabetes extend beyond the toll it takes on those with the disease and their families and friends. Diabetes also exacts a major toll on the U.S. economy. This study analyzes these economic effects and assesses whether continuing the Special Diabetes Program, which funds research into treating and curing type 1 diabetes through the National Institutes of

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[1] Support for research used in this study was generously provided by JDRF. The views and analyses expressed here are solely those of the authors.

[2] Centers for Disease Control and Prevention (2012). Nichols et al. (2007).

[3] Mayer-Davis et al. (2012); Dabelera, D. et al. (2012).

[4] United Health (2010).

[5] Centers for Disease Control and Prevention. (2012).

Health (NIH), could materially contribute to ameliorating the adverse economic impacts associated with diabetes.

Our key findings:

- Treating people with diabetes cost Americans $128 billion in 2007 [6] or about 0.9 percent of GDP. By 2020, these medical costs are expected to reach $410 billion[7] or an estimated 1.8 percent of a projected GDP of $23.4 trillion in 2020.[8]

- Diabetes also imposes large, non-medical costs on the economy. There are productivity losses associated with missed work, permanent disabilities and premature deaths from diabetes and its complications. These non-medical costs totaled some $65 billion in 2007[9] which equaled 0.5 percent of U.S. GDP in that year. Based on people's average earnings in 2007 ($44,458), we estimate these costs would have covered the wages and salaries of an additional 1,462,054 full-time workers. [10]

- By 2020, these non-medical, economic costs are expected to reach $196 billion[11] or more than 0.8 percent of a projected GDP of $23.4 trillion in that year. Assuming historical trends in earnings, we estimate the foregone economic production related to diabetes in 2020 would cover the wages and salaries of 2,644,824 full-time workers in that year.

- All told, the medical and non-medical costs of diabetes came to $193 billion in 2007[12] or 1.4 percent of GDP. By 2020, these total costs are expected to reach $606 billion[13] or 2.6 percent of projected GDP in 2020.

- The NIH currently provides $150 million per-year in such support through the Special Diabetes Program (SDP), as well as additional funds through other grant programs. The SDP has supported the establishment of new research infrastructure and funded new research programs that already have advanced our basic knowledge of diabetes and its

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[6] Dall et al. (2009).

[7] United Health. To estimate the costs in 2020, we start with the 2007 costs reported by Dall et al and apply the growth rates in costs from 2007 to 2020 projected by the United Health study.

[8] Congressional Budget Office (August 2010).

[9] United Health (2010).

[10] BLS, Employment and Wages, Annual Averages 2007, Table 1. www.bls.gov/cew/ew07table1.pdf .

[11] Dall et al. (2009); United Health (2010).

[12] Dall et al. (2009).

[13] *Ibid*.; United Health (2010).

causes, led to improved treatments and screening for T1D, and advanced research into potential cures.

- With 15 years of NIH support for T1D research, the likelihood of additional breakthroughs will increase if the program is renewed. If those advances can reduce the incidence and severity of T1D by just 10 percent by 2020, we estimate that the savings in medical costs would exceed $2.6 billion per-year, including $1.9 billion in savings for Medicare and Medicaid, plus another $2.2 billion in annual non-medical economic savings, for a total savings of $4.8 billion a year. In this scenario, we estimate the advances will produce an annual rate of return of 163%, year after year.

- If spillovers from these advances reduce the incidence and severity of T2D by just 5 percent in 2020, we estimate that would save nearly $17.4 billion per-year in medical costs, including more than $12.3 billion per-year in Medicare and Medicaid costs, plus nearly $7.5 billion per-year in non-medical economic costs.

- The estimated annual savings from a 5 percent reduction in the incidence and severity of T2D by 2020 would be more than 8.5 times the total projected NIH funding for SDP funded research over 22 years.

- NIH support for T1D research is also critical to the progress of the diabetes R&D programs of private pharmaceutical firms: Researchers have found that a one percent increase in NIH-funded basic research leads to a 2.5 percent increase in private R&D spending, with a seven-year lag.[14]

Based on this analysis, we conclude that not continuing the SDP for research in type 1 diabetes would be highly ill-advised and ultimately very costly for both the millions of Americans suffering from the disease and U.S. taxpayers.

II. The Medical and Economic Challenge of Diabetes in the United States

The Varieties of Diabetes and the Medical Complications Associated with the Disease

"Diabetes" covers a number of different forms of the disease, although all are characterized by some defect in the production of insulin, how insulin acts in the body, or both. Type 1 diabetes, formerly called juvenile diabetes because it often is diagnosed in childhood, develops when the body's immune system destroys the beta cells in the pancreas that secrete the insulin hormone. We all need appropriate levels of insulin, because it metabolizes glucose and

[14] Congressional Budget Office (2006).

enables people to derive energy from food. Since pancreatic beta cells are the only cells in our bodies that can produce insulin, people with T1D have to depend on regular injections of external insulin.[15]

The most common form of the disease is Type 2 diabetes, which usually manifests in adulthood, although it can also affect children and adolescents. T2D typically begins as insulin resistance, a disorder in which cells do not properly absorb and use insulin. In combination with abnormal pancreatic beta cell function, this resistance results in an insulin deficiency; and as the need for insulin increases, the pancreas gradually loses its ability to produce the hormone.[16] Studies have found that the onset of T2D is correlated with obesity, physical inactivity, a family history of diabetes, and impaired glucose metabolism. T2D may also be associated with a personal history of gestational diabetes, a form of glucose intolerance that can occur during pregnancy.[17]

Generally speaking, diabetes is caused by a loss of functional beta cell mass, as in an autoimmune process in T1D or the increased need for insulin seen in T2D. While T1D and T2D have different causes, the complications are often the same. Diabetes is a growing health concern, because the condition is a major cause of other serious conditions such as heart disease, stroke, kidney failure, hypertension, blindness, nervous system disorders and severe circulatory dysfunctions requiring amputations.[18] Persistent elevation of blood sugar levels slowly damages many organs including the heart, kidneys, nerves, and eyes. Given the high costs of these effects and their treatments, returns on development of new treatments for diabetes can be very large.

As detailed by the Centers for Disease Control[19], complications from diabetes include:

- *Heart disease and stroke*. Adults with diabetes die from heart disease at rates two-to-four time greater than adults without diabetes.[20] Similarly, the risk of strokes is two to four times greater for people with diabetes. These higher risks arise from the damage that a high blood glucose level does to blood vessels.

- *Kidney disease*. Diabetes is also a leading cause of kidney failure, accounting for 44 percent of new cases of kidney failure in the United States in 2008. In 2008, over 48,000

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[15] Centers for Disease Control and Prevention (2012).

[16] *Ibid*.

[17] In addition, other types of diabetes can arise from certain genetic conditions, surgeries, medications, infections, pancreatic disease, and other illnesses. Centers for Disease Control and Prevention (2012).

[18] *Ibid.*

[19] *Ibid.*

[20] *Ibid.* Heart disease is noted on 68 percent of diabetes-related death certificates for people age 65 and older, and stroke is noted on 16 percent of those death certificates.

people with diabetes began treatment for end-stage kidney disease, and some 202,000 diabetics with end-stage kidney disease relied on chronic dialysis or kidney transplants.

- *Hypertension*. During the years 2005 to 2008, 67 percent of people with diabetes aged 20 years or older had blood pressure equal to or greater than 140/90 or relied on prescription medications for hypertension.

- *Blindness and eye problems*. Diabetes is the leading cause of new cases of blindness among adults aged 20-74 years. Over the years 2005 to 2008, 4.2 million people with diabetes age 40 and older had diabetic retinopathy, including 655,000 people had advanced retinopathy that can lead to severe vision loss.

- *Nervous system disease*. Between 60 percent and 70 percent of people with diabetes also have mild to severe damage to their nervous system. The consequences of this damage include impaired sensation or pain in feet or hands, slowed digestion, carpal tunnel syndrome, erectile dysfunction, and other nerve problems.

- *Amputations*. Severe forms of diabetic nerve disease are a major contributing cause of lower-limb amputations. More than 60 percent of non-traumatic, lower-limb amputations occur in people with diabetes, including some 65,700 people in 2006.

Finally, people with diabetes are more susceptible to many other illnesses, including depression, biochemical imbalances, pneumonia, influenza, and severe gum disease.

People with T1D face additional risks. T1D is an autoimmune disorder in which a person's immune system attacks his or her own pancreas and destroys the cells that produce insulin. People with T1D must carefully balance their insulin doses with dietary restrictions and daily activities, and they face the constant danger of life-threatening emergencies. Since many people with T1D are diagnosed as children or young adults, they must manage the disease for many decades, which in turn increases the risk of complications. Among women with T1D that is poorly-controlled before conception and in the first trimester of their pregnancy, major birth defects occur in 5 percent to 10 percent of such cases and spontaneous abortions occur in 15 percent to 20 percent of cases.[21] People with T1D are also much more likely to develop celiac disease, another autoimmune disorder that affects their digestive systems. People with this disease cannot tolerate gluten, a protein found in wheat, rye, barley and triticale; and the disease damages their intestines and ability to absorb nutrients. One in every 10 people with T1D develops celiac disease, compared to one in every 100 people in the rest of the population.[22]

[21] National Diabetes Information Clearinghouse (2011).

[22] JDRF"Double Diagnosis: Living with Type 1 Diabetes and Celiac Disease."

Adolescents with T1D also have an increased risk of developing eating disorders[23]. People with T1D also have a heart attack risk that is ten times more likely than those without diabetes.[24].

These various complications not only reduce the average lifespan of people with diabetes, they also increase their demands on the healthcare system and the attendant costs. Compared to the rest of America, people with diabetes, especially those with T1D, visit doctors' offices, emergency rooms, and hospitals on both an inpatient and outpatient basis more often. (Table 1, below) For example, the data show that adults age 45 to 64 with T1D visit their physicians' offices 2.1 times for every physician office visit by an adult the same age without diabetes, entailing significant costs for the health care system.

Table 1. Ratio of Annual Heath Care Use by Adults Age 45-64 Diagnosed with Diabetes, and by Medical Complications Linked to Diabetes, Compared to Other Americans, 2007[25]

	Physician Office Visits		Outpatient Visits		Emergency Room Visits		Hospital Inpatient Days	
	T1D	T2D	T1D	T2D	T1D	T2D	T1D	T2D
Diagnosed Diabetes Patients	**2.1**	**1.9**	**2.2**	**2.1**	**1.8**	**1.9**	**3.7**	**2.7**
Complications								
Neurological	7.9	4.9	6.2	4.1	5.4	3.7	6.0	5.3
Peripheral vascular	3.5	2.9	5.6	4.3	4.0	2.5	10.9	5.8
Cardiovascular	1.7	2.0	1.9	2.1	3.1	3.0	7.1	6.1
Renal	4.1	2.9	4.0	2.9	3.1	2.8	15.3	6.7
Endocrine	1.3	1.4	1.3	1.4	14.7	8.3	23.0	9.8
Ophthalmic	5.7	3.6	6.2	4.0	2.3	2.3	7.4	7.2
Other diabetes	4.1	3.1	6.6	4.4	2.8	2.7	12.9	10.3
Other conditions	1.4	1.4	1.4	1.4	1.6	1.7	2.6	1.9

The Incidence and Prevalence of Diabetes

Across the world, an estimated 285 million adults have been diagnosed. Moreover, those numbers are expected to grow rapidly as the world's population ages, as urbanization increases, and as obesity and sedentary lifestyles become more common.[26] The United States has the third highest concentration of people with diabetes. Some 17.6 million Americans in 2007 were

23 Rydall, Anne C. et. al. (1997).

24 National Institutes of Health (2011).

25 Dall et al. (2009).

26 Zhang et al. (2010).

diagnosed diabetics, and another 6.5 million more Americans are thought to have diabetes but have not been diagnosed as such.[27] (Table 2, below) By these classifications, 5.8 percent of the current U.S. population were diagnosed with a form of diabetes, and another 2.2 percent of the population had undiagnosed diabetes. All told, these data tell us that in 2007, more than 24 million Americans or 8.0 percent of the U.S. population had diabetes.

Moreover, experts from United Healthcare's Center for Health Reform and Modernization predict that diabetes will continue to grow faster than the overall population. By 2020, they estimate that the number of Americans with diagnosed diabetes will reach nearly 29 million, and another 10.5 million people will have undiagnosed diabetes. All told, they expect that by 2020, more than 39 million Americans, or 11.7 percent of the population, will have diabetes. (Table 2, below)

Table 2. Incidence of Diabetes in the United States, 2007 and 2020[28]

	2007		**2020 (estimated)**	
	Cases	**Share of U.S. Population**	**Cases**	**Share of U.S. Population**
Total Diabetes	**24,100,000**	**8.0%**	**39,200,000**	**11.7%**
Diagnosed diabetes	17,600,000	5.8%	28,700,000	8.6%
Type 1 diabetes	1,000,000	0.3%	1,300,000	0.4%
Type 2 diabetes	16,600,000	5.5%	27,500,000	8.2%
Undiagnosed diabetes	6,500,000	2.2%	10,500,000	3.1%
U.S. Population	301,500,000	100.0%	335,000,000	100.0%

Of the 10 leading causes of death in the United States, diabetes ranked seventh in the number of deaths and third in the number of cases. (Table 3, below) The Centers for Disease Control and Prevention report that from the 24.1 million Americans with diabetes in 2009, 68,905 died of the disease that year. 2011 data indicate that diabetes caused more than 70,000 deaths in that year and was a contributing factor in an additional 160,000 deaths.[29]

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[27] Dall et al. (2009)

[28] *Ibid.*; United Health (2010).

[29] Centers for Disease Control and Prevention (2012).

Table 3. Ten Leading Causes of Death and Their Incidence, 2009, by Numbers of Deaths[30]

Cause of Death	Deaths	Cases
Heart Disease	595,444	74,521,000
Cancers	573,855	19,451,400
Chronic Lower Respiratory Diseases	137,789	35,610,000
Stroke	129,180	6,266,000
Accidents	118,043	NA
Alzheimer's Disease	83,308	5,100,000
Diabetes	**68,905**	**24,100,000**
Nephritis, Nephrotic Syndrome, Nephrosis	50,472	3,631,000
Influenza and Pneumonia	50,003	4,000,000
Suicide	37,793	1,052,000

III. The Costs of Diabetes

Diabetes imposes a large economic burden on the national healthcare systems of almost every country, with the United States spending more, both per-patient and overall, than any other nation.[31] These costs include medical costs such as hospital stays, emergency room visits, doctor office visits, drugs, and medical treatments and supplies. The economic costs of diabetes also include non-medical costs, such as lost productivity due to interruptions during the work day, absences from work, disability, or premature death.[32]

Researchers have calculated that diabetes costs Americans $193 billion in 2007, the equivalent of 1.4 percent of GDP in that year.[33] The total includes $128 billion in medical costs, or 0.9 percent of GDP, and $65 billion in non-medical, economic costs associated with people with undiagnosed cases of diabetes as well as those already diagnosed with the disease. (See Table 4, Panel 1, below) These non-medical costs were equivalent to 0.5 percent of GDP. As

[30] Center of Disease Control and Prevention (2011).

[31] Zhang et al. (2010). In terms of overall expenditures on diabetes, the United States is followed by Germany, Japan, France, and Canada

[32] Diabetes, especially T1D, also can interfere with a person's education. A 2012 study found that compared to healthy peers, people with diabetes, on average, complete 0.675 fewer years of formal education and are eight to 13 percentage points less likely to attend college. As a consequence, the annual earnings of people with diabetes, on average, are $1,500 to $6,000 less than their peers without diabetes. Fletcher and Richards (2012)

[33] Dall et al. (2009).

these non-medical costs are estimates of foregone productivity and production, in the absence of these diabetes-related effects, GDP would have been 0.5 percent higher that year. And based on the average earnings of Americans in 2007 of $44,458, we estimate these non-medical costs would have covered or supported the wages and salaries of an additional 1,462,054 full-time workers.[34] (Table 4, Panel 2, below)

Moreover, based on projections of the growth of diabetes and its costs by the Center for Health Reform and Modernization, by 2020 those U.S. costs will reach $606 billion or 2.6 percent of a GDP of $23.4 trillion in that year as estimated by the Congressional Budget Office.[35] This total includes $410 billion in medical costs, the equivalent of nearly 1.8 percent of the $23.4 trillion GDP projected for 2020, and $196 billion in non-medical costs. These $196 billion in non-medical costs would be equivalent to more than 0.8 percent of the GDP projected for 2020. Assuming that historic trends in earnings growth persist, we further estimate that the foregone economic production associated with diabetes in 2020 would cover the wages and salaries of 2,644,824 full-time workers in that year.

Table 4. Economic Costs and Burdens Attributed to Diabetes, 2007-2020[36]

Panel 1:
Costs of Diabetes in the U.S., 2007 and Estimated for 2020 ($ billions)

	2007			Estimate for 2020		
	Total	**Medical**	**Non-Medical**	**Total**	**Medical**	**Non-Medical**
Total	**$193**	**$128**	**$65**	**$606**	**$410**	**$196**
Diagnosed diabetes	$174	$116	$58	$544	$373	$171
Type 1 diabetes	$15	$11	$4	$48	$26	$22
Type 2 diabetes	$159	$105	$54	$496	$347	$149
Undiagnosed	$19	$12	$7	$62	$37	$25

Panel 2:
Costs of Diabetes as Shares of GDP and Foregone Employment, 2007 and Estimated for 2020

	2007			Estimate for 2020		
	Total	**Medical**	**Non-Medical**	**Total**	**Medical**	**Non-Medical**

[34] BLS, Employment and Wages, Annual Averages 2007, Table 1. Total coverage (UI and UCFE) by ownership: Establishments, employment, and wages, 1998-2007 annual averages, at http://www.bls.gov/cew/ew07table1.pdf.

[35] Congressional Budget Office (2010).

[36] United Health (2010); Dall et al. (2009). As noted earlier, we use the estimated medical costs and non-medical costs of T1D and T2D patients in 2007 derived by Dall et al in their 2009 study. To estimate these costs for 2020, we apply the projections of the likely increases in these costs from 2007 to 2020 reported in the United Health study.

Total Costs	$193	$128	$65	$606	$410	$196
Share of GDP	1.4%	0.9%	0.5%	2.6%	1.8%	0.8%
Foregone Employment	--	--	1,462,054	--	--	2,644,824

In the aggregate, T2D accounted for nearly 55 percent of the total costs of the disease in 2007 and almost 68 percent of the medical costs. On a per-case basis, however, the medical and non-medical costs associated with T1D, $14,900 per-case in 2007, were 55 percent greater than those arising from T2D at $9,584 per-case, reflecting mainly the complications that often accompany T1D. (Table 4, Panel 3, below) Researchers estimate that by 2020, an average case of T1D will cost nearly twice as much to treat, at $38,600 per-case, as a case of T2D at $18,060.

Panel 3:
Total Costs Per-Case of Diabetes in the U.S., 2007 and Estimated for 2020 ($)

	2007			Estimate for 2020		
	Total	Medical	Non-Medical	Total	Medical	Non-Medical
Total Diabetes	**$8,008**	**$5,311**	**$2,697**	**$15,459**	**$10,459**	**$5,000**
Diagnosed diabetes	$9,886	$6,591	$3,295	$18,955	$12,997	$5,958
Type 1 diabetes	$14,900	$10,500	$4,400	$38,600	$21,000	$17,600
Type 2 diabetes	$9,584	$6,355	$3,229	$18,060	$12,632	$5,428
Undiagnosed	$2,923	$1,846	$1,077	$5,905	$3,524	$2,381

Epidemiologists predict that the total costs of diabetes will increase 214 percent from 2007 to 2020, and the costs per case or per patient will nearly double. (Panel 4, below) To begin, the number of Americans expected to be diagnosed with T1D or T2D, along with cases of undiagnosed diabetes, is expected to rise sharply. Moreover, unless new, cost-saving advances occur as a result of public and private supported research, the costs of treating the illness and its complications will grow faster than the population or economy. The result: The total costs of diabetes are expected to rise from 1.4 percent of GDP in 2007 to 2.6 percent of GDP in 2020.

Panel 4:
Projected Growth in Costs of Diabetes in the U.S., Overall and Per Patient, 2007-2020

	United States			Per Patient		
	Total	Medical	Non-Medical	Total	Medical	Non-Medical
Total Diabetes	**214%**	**220%**	**201%**	**93%**	**97%**	**85%**
Diagnosed diabetes	213%	222%	195%	92%	97%	81%
Type 1 diabetes	224%	150%	400%	159%	100%	300%
Type 2 diabetes	212%	229%	178%	88%	99%	68%
Undiagnosed	226%	208%	257%	102%	91%	121%

As noted in Panel 3, the per-patient costs of T1D are expected to increase 159 percent from 2007 to 2020, compared to 88 percent increases projected for T2D. This acceleration in the costs of T1D is driven largely by the high costs of hospital care and the fast-rising non-medical costs associated with an illness that mainly affects young people. This underscores the urgency of discovering new treatments to delay or reduce the severity of T1D, reduce the risks of medical complications, or even cure the disease could produce large economic savings and benefits.

The Components of the Medical and Non-Medical Costs of Diabetes

The current costs of the various aspects of living with diabetes are presented in Table 5 below. In 2007, the hospital-related costs of living with T1D accounted for 52 percent of all of the costs associated with the disease, premature deaths accounted for another 15 percent of costs, and absenteeism and other reduced productivity at work ("presentee-ism") accounted for another 9 percent. In contrast, hospital costs accounted for just 36 percent of all costs associated with T2D, with drugs accounting for more than 16 percent of costs, premature deaths accounted for 15 percent, and absenteeism and other productivity losses accounted for 13 percent of costs.

Table 5: Economic Costs Attributed to Diagnosed Cases of Diabetes in 2007[37]

	All Diagnosed Cases	T1D	T1D Shares	T2D	T2D Shares
Total Costs	**$174,418,000,000**	**$14,926,000,000**	**100%**	**$159,492,000,000**	**100%**
Medical costs	$116,258,000,000	$10,548,000,000	70.7%	$105,710,000,000	66.3%
Institutional care	$65,831,000,000	$7,769,000,000	*52.1%*	$58,062,000,000	*36.4%*
Outpatient care	$22,743,000,000	$1,237,000 000	*8.3%*	$21,505,000,000	*13.5%*
Outpatient drugs	$27,684,000,000	$1,541,000,000	*10.3%*	$26,143,000,000	*16.4%*
Non-medical costs	$58,160,000,000	$4,378,000,000	29.3%	$53,782,000,000	33.7%
Absenteeism	$2,597,000,000	$127,000,000	*0.9%*	$2,470,000,000	*1.5%*
Presentee-ism	$19,955100,000	$1,240,000,000	*8.3%*	$18,715,000,000	*11.7%*
Disability	$7,949,000,000	$674,000,000	*4.5%*	$7,276,000,000	*4.6%*
Premature mortality	$26,902,000,000	$2,298,000,000	*15.4%*	$24,604,000,000	*15.4%*

Further analysis of the distribution of these costs based on age shows that the costs per patient rise sharply later in life for those with T1D, while the per-patient costs of those with T2D remain relatively stable throughout their lives. (Table 6, below) T1D and its complications cost $36,349 per-year, per-patient over the age of 65, compared to $8,649 per-year per-patient from infancy to age 44 and $13,881 per-year per patient age 45 to 64 years old. By contrast, the costs per-patient, per-year for those with T2D vary, averaging $9,584 throughout life. The high costs of T1D in the elderly are almost entirely medical-related costs, averaging $35,365 per-person, per-year, and reflect the serious, cumulative complications often associated with the condition.

Table 6: Annual Costs Arising from Diagnosed Cases of Diabetes, Per Patient, by Age, 2007[38]

	All Diagnosed Cases	T1D	T2D

[37] Dall et al. (2009).

[38] *Ibid*.

Total Costs Per Case	**$9,886**	**$14,900**	**$9,584**
Age 0 to 44	$9,099	$8,649	$9,202
Age 45 to 64	$9,868	$13,881	$9,701
Age 65+	$10,473	$36,349	$9,815
Medical Costs Per Case	$6,591	$10,500	$6,355
Age 0 to 44	$3,808	$4,044	$3,755
Age 45 to 64	$5,094	$8,169	$4,966
Age 65+	$9,713	$35,365	$9,061
Non-Medical Costs Per Case	$3,295	$4,400	$3,229
Age 0 to 44	$5,291	$4,605	$5,447
Age 45 to 64	$4,774	$5,712	$4,735
Age 65+	$760	$984	$754

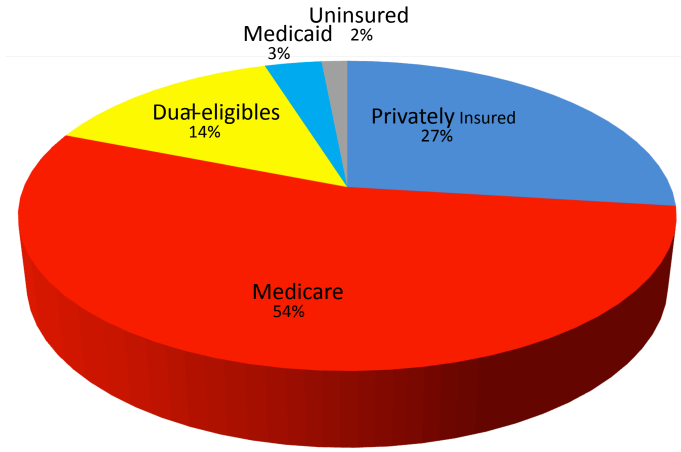
All of these estimates cover only diagnosed cases of diabetes. Experts estimate, however, that nearly 10 percent of the total costs of the conditions, or about $19 billion in 2007, are associated with people with yet-undiagnosed cases of the disease. Nearly $12 billion of these costs are thought to have been medical-related, primarily hospital services. The remaining $7 billion is costs represent non-medical costs, primarily reduced performance at work.

Who Pays the Bills for Treating Diabetes

The Center for Health Reform and Modernization estimates that the health-related costs associated with diabetes will total $2.766 trillion over the decade, 2011 to 2020. Medicare will account for 54 percent of these costs, Medicaid will cover about 3 percent, and patients eligible for both Medicare and Medicaid will account for another 14 percent of the costs. (Figure 1, below) In short, taxpayers bear 71 percent of the medical costs associated with diabetes through their funding of the Medicare and Medicaid programs. Private insurance picks up 27 percent of the medical costs of diabetes, while uninsured people not eligible for Medicare or Medicaid account for the remaining 5 percent of these costs, which are then paid for by the patients themselves or picked up by hospitals and physicians.

Figure 1. Medical Spending on Diabetes, By Coverage, 2011-2020[39]

[39] United Health (2010).



IV. NIH Support for Research on Type 1 Diabetes

Since the 1990s, Congress has recognized diabetes as a major public health concern and allocated significant federal funding for research. Under the Balanced Budget Act of 1997, Congress created the Special Diabetes Program (SDP) to support basic research into ways of preventing, treating, and one day, hopefully, curing T1D and its complications. The Program is a targeted research effort designed to foster scientific collaborations among the Institutes and Centers of the National Institutes of Health, the Centers for Disease Control and Prevention, and the broader scientific research community. The Program's goals envisage research to identify the genetic and environmental causes of T1D and develop cell replacement therapies. The program also seeks to attract new talent and to apply new technologies, in order to prevent or reverse TID and reduce its complications, and prevent or reverse episodes of dangerously low blood sugar ("hypoglycemia").[40] The Program was originally funded at $30 million a year and later increased. It currently is funded at $150 million a year through FY2013.[41]

While this analysis focuses on the cost-effectiveness of the $150 million research funding for T1D through SDP, NIH support for research into diabetes totaled some $1,076 million in FY 2011 (including the $150 million for T1D research through SDP and approximately $250 million through academic grants) or 3.5 percent of the NIH budget.[42]

A review of NIH support in 2010-2011 for the ten leading causes of death among Americans shows that NIH research support for diabetes comes to just $45 per-patient, less than

[40] National Institutes of Health (2011). "Special Statutory Funding Program for Type 1 Diabetes Research"; and National Institute of Diabetes and Digestive and Kidney Diseases.

[41] *Ibid.*

[42] National Institutes of Health (2010). "Special Statutory Funding Program for Type 1 Diabetes Research – Progress Report." National Institutes of Health (2012).

any of the other leading causes of death except chronic lower respiratory diseases. (Table 7, below) Based on mortality rates, however, diabetes receives the highest level of NIH research support, at $15,616 per-death.

Table 7. NIH Support for Research into the 10 Leading Causes of Death: Total Funding, Funding Per-Patient and Per-Death, 2010-2011[43]

Disease/Condition	NIH Funding (millions)	NIH Funding Per Patient	NIH Funding Per Death
Heart Disease	$3,962	$53	$6,654
Cancers	$8,046	$414	$14,021
Chronic Lower Respiratory Diseases	$351	$10	$2,547
Stroke	$317	$51	$2,454
Accidents	$734	--	$6,218
Alzheimer's Disease	$448	$88	$5,378
Diabetes	**$1,076**	**$45**	**$15,616**
Nephritis, Nephrotic Syndrome, Nephrosis	$599	$152	$11,868
Influenza and Pneumonia	$771	$193	$15,419
Suicide	$49	$47	$1,297

Progress in Treating and Managing Diabetes

Several decades of research into the causes, course and management of diabetes and the health conditions that often accompany it, notably heart and kidney disease, have produced important advances. Since the 1950s, the share of Americans with T1D who died within 20 years of being diagnosed has fallen from 20 percent to just 3.5 percent, and the share who die within 25 years of their initial diagnosis has declined from 33 percent to just 7 percent.[44] These major improvements have been accompanied by substantial progress in the quality as well as the length of life of those suffering from T1D.[45] T2D, which accounts for 90 percent or more of diagnosed cases of diabetes, can be managed and controlled more easily than T1D and sometimes can be prevented through diet and exercise. The likelihood of serious complications also is greater with T1D than T2D, in part because T1D strikes in childhood or adolescence.[46]

Like virtually all medical research efforts, progress in diabetes research has required considerable time and investments. For example, it took 10 years for the Diabetes Control and

[43] National Institutes of Health (2012); World Trade Organization (2008); Gillum et al. (2011).

[44] National Institutes of Health (2010). "Type 1 Diabetes Fact Sheet."

[45] Lenord (2012).

[46] Dall et al. (2009).

Complications Trial, starting in 1983, to establish that intensive blood-sugar control reduces the risks of complications involving patients' eyes, kidneys, and nerves. It took an additional decade for the follow-on Epidemiology of Diabetes Interventions and Complications trial to assess the effect on the risks of cardiovascular complications in T1D patients.

SDP Research and the Development of New Therapies for T1D

The Special Diabetes Program has provided long-term support to a large number of research projects, many of which have already produced substantial advances. For example, the Program has funded the Type 1 Diabetes Genetics Consortium, which developed new technologies that identified nearly 50 genes or genetic regions that influence a person's risk of developing T1D. Identifying and understanding the genetic contributors and influencers for T1D, in turn, has helped scientists to better understand the disease, identify individuals at risk, develop and test new prevention strategies, and design clinical trials to test personalized interventions for patients with similar risk profiles. In time, these advances may enable scientists to safely prevent T1D in some people and restore normal beta cell function in others.[47] The Program also supports the Beta Cell Biology Consortium, an international collaboration studying insulin-producing cells in hopes of developing new cell-based therapies to treat T1D, as well as another consortium of research institutions working to create new animal models for the study of the onset of complications associated with T1D.[48]

In addition, the Program has provided the critical support used by the Clinical Islet Transplantation Consortium to develop new procedures that have dramatically improved the success rate of islet transplants. For example, the Program provided 98 percent of the support needed for Phase III trials that are expected to form the basis for an application for FDA approval of new islet cell transplant therapy. As a result, 471 patients with T1D received islet implants from 2000 to 2005, more than the number of people with diabetes receiving islet transplants in the preceding 30 years of the procedure. Scientists hope to build on these advances in ways that may make islet transplants a common mode of treatment.[49]

Support for Early Identification and Treatment of T1D

The Program is also responsible for the TrialNet project, which screens about 20,000 people considered at risk of developing T1D each year. Screening is the first step on the pathway to prevention and provides an important opportunity for intervention at an early stage. Because persons related to people with T1D are 10-100 times more likely to develop the disease than the general population, TrialNet provides screening free of charge to all relative of people

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[47] National Institutes of Health (2010). "Special Statutory Funding Program for Type 1 Diabetes Research – Progress Report."

[48] JDRF (n.d.). "The Special Diabetes Program: Advancing Research and Improving Lives on the Path to a Cure."

[49] Shapiro et al. (2005).

with T1D. The Program also supports SEARCH, a national multi-center study to examine the current status of diabetes among children and adolescents. SEARCH seeks to develop a uniform classification of types of childhood diabetes, estimate the number of new and existing cases of childhood diabetes, identify the clinical characteristics of the different types of diabetes in youth and how they evolve, and categorize the complications of the disease and the impact on the quality of life of children and adolescents.[50] More than 6 percent of American children aged 0 to 19 years – more than 5 million children – have participated in the program.

The Program also has provided support for the Environmental Determinants of Diabetes in the Young (TEDDY) project. This project is building the most comprehensive database of newborns at high risk of developing T1D by following more than 7,000 infants with genetic markings for the disease, from infancy to age 15. Tracking dietary and health data and collecting regular stool, blood, and other samples, the project aims to identify environmental factors that trigger the disease and, on this basis, develop strategies to prevent, delay, and reverse it. Scientists also hope to use this knowledge to develop a vaccine to prevent T1D.[51]

Other Support for New Treatments

Other projects supported by the Special Program include a network of clinical centers that are testing and evaluating new technologies for managing T1D in children.[52] In addition, the Program funds the Diabetes Retinopathy Clinical Research Network, a collaborative research network of clinicians and researchers at more than 160 institutions, which helped determine that a therapy originally developed for cancer could, in some cases, halt and even reverse the progression of diabetes-related vision loss. Numerous other Special Program-supported projects have yielded important advances. The program funded research testing the use of continuous glucose monitors, which helped demonstrate their benefits in enabling patients to maintain healthy levels of glucose and thereby reduce the likelihood of developing complications. Support from the Program was also critical to the recent success of researchers from several health centers who have developed and tested artificial pancreas systems which continuously monitor glucose levels and deliver appropriate doses of insulin.[53] Research and development is underway to develop a version of this system that could be available in the future for T1D patients to use in their daily lives.

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[50] Centers for Disease Control and Prevention, SEARCH for Diabetes in Youth. Website.

[51] *Ibid*.

[52] Juvenile Diabetes Research Foundation (n.d.). "The Special Diabetes Program: Advancing Research and Improving Lives on the Path to a Cure."

[53] Mayo Clinic (2011). See also, http://corporate.uvahealth.com/news-room/archives/uva-artificial-pancreas-gets-first-u.s.-outpatient-test.

Finally, numerous studies have found a strong positive relationship between such public support for basic research and R&D investments by private pharmaceutical firms.[54] Researchers have shown that a one percent increase in NIH-funded research leads to a 2.5 percent increase in private R&D spending, with a lag of about seven years while the basic research is conducted and its findings published.[55] Studies also show that increases in public spending for basic research are associated with eventual increases in the approval of new molecular entities, with a lag of 18 years between the initial funding for the basic research and FDA approval of additional new drugs.[56] In 2011, for example, researchers reported the development of DiaPep277, a new drug currently undergoing phase three trials that may prevent beta cell destruction in T1D patients and, thereby, allow beta cells to continue to secrete insulin for up to two years following a T1D diagnosis.[57]

V. Assessing the Benefits of NIH-Supported Diabetes Research

While the Special Diabetes Program has provided support for many promising lines of research and development, quantifying the economic benefits of the Program is challenging. To begin, medical research and associated clinical trials often require many years to show results. While the Program has made significant contributions to the current basic understanding of T1D, many of its projects continue to focus on data collection, identifying basic causes, and attracting talent to research into T1D.[58] Nevertheless, we can knowledgeably speculate about some of the Program's benefits.

A Case Study: SDP & Prevention of T1D

The Special Diabetes Program is advancing research that could prevent or delay the onset of T1D. An example is TrialNet, the program that screens people at risk of developing T1D and conducts clinical trials testing potential therapies to prevent onset of the disease. TrialNet offers free screenings to relatives of people with T1D, people whose chances of developing the disease are 10-to-100 times greater than those with no family history. The screening is designed to detect the auto-antibodies that lead to T1D which, as recent clinical trials have established, may appear up to 10 years before symptoms of the disease become apparent. At the same time, TrialNet is conducting clinical trials of compounds that may enable those with antibodies to delay the onset

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54 Congressional Budget Office (2006).

55 Ward and Dranove (1995); CBO (2006).

56 *Ibid.*; Toole (2000); DiMasi et al (2003).

57 "Advances in Treating Type 1 Diabetes: Drugs Show Promise for Preserving Body's Ability to Produce Insulin," June 28, 2011, http://www.diabetes.org/for-media/2011/advances-in-treating-type-1-sci-sessions-2011.html .

58 National Institutes of Health (2010). "Special Statutory Funding Program for Type 1 Diabetes Research – Progress Report."

of the disease, moderate its eventual severity, and avoid some of the serious complications which often accompany it.[59]

As shown earlier, total costs of T1D are estimated around $14,900 per case per year, with some 70 percent attributed to medical costs. Based on the TrialNet Progress Report, approximately 5.3 percent of those screened were found to be auto-antibody positive.[60] TrialNet has screened some 100,000 participants, which means it has identified approximately 5,300 people with the auto-antibodies that signal the development of T1D. Early results of the NIDDK studies suggest that oral insulin may delay insulin dependency for four years in people with high insulin auto-antibody levels, and TrialNet trials are currently ongoing to confirm this observation.[61] If we assume that all of those identified are young and consider only the medical costs, the annual savings from delaying the onset of T1D will be $4,044 per-person. (Table 6, above) If oral insulin therapies delay the onset for an average of four years, the four-year savings from the 5,300 people identified by TrialNet as possessing the auto-antibodies would come to $86 million. If we apply the total average economic cost of $14,900 per-person with T1D, the potential savings from this one project come to $316 million (5,300 x 4 x $14,900 = $315.8 million) or 16.7 percent of the Special Program's total 15-year funding of $1.89 billion.

In addition to TrialNet's 100,000 initial screenings, the program also screens up to 20,000 subjects per year through its "Natural History Study." This study provides the framework for the identification, risk characterization and potential recruitment of subjects into the trials. Applying the current results that have found 5.3 percent of subjects with the auto-antibodies for T1D, TrialNet should be able to identify an additional 1,060 positive auto-antibody patients each year. About 15,000 children and 30,000 people in total are diagnosed with T1D each year in the United States. TrialNet in its current form, therefore, can detect 3.5 percent of new cases years before a normal diagnosis. The economic benefits and savings associated with that early identification and appropriate intervention would come to between $4.3 million and $15.7 million per-year, or another $17 million to $63 million over four years.[62]

Spillover benefits from T1D Research and Advances

The advances in understanding the origins and mechanisms of T1D also have large, potential spillover benefits for other areas. For example, scientists believe that the artificial pancreas now being used on a small scale to regulate abnormal blood sugar levels in T1D patients may eventually be applied to people with T2D, who comprise 90 to 95 percent of all

[59] Type 1 Diabetes TrialNet (2011). "TrialNet Reaches Important Milestone – Screens 100,000 People for Type 1 Diabetes." Type 1 Diabetes TrialNet (2011). "Aided by Relatives of those with Type 1 Diabetes, TrialNet Researchers Close in on Prevention."; and Lenord (2012).

[60] Type 1 Diabetes TrialNet (2011). "Progress Report – Type 1 Diabetes TrialNet."

[61] Type 1 Diabetes TrialNet, (2011). "Oral Insulin Prevention Study Surpasses Midway Enrollment Goal – Thousands More Need To be Screened."

[62] Skyler et al. (2008).

Americans with diabetes. More generally, progress in early detection of T1D enables physicians to intervene to lower blood glucose levels, blood pressure and other risk factors which otherwise would lead to circulatory system damage. Early detection also enables physicians to screen for and treat other conditions such as retinopathy.[63] Moreover, the savings will be enormous if, as expected, these early interventions lead to lower rates of complications that threaten patients with T2D as well as T1D, including heart attacks, strokes, nerve damage, and the diseases of the eyes and kidneys.[64]

The NIH-supported research for T1D may produce even broader spillovers. NIH scientists have confirmed that some of the genes associated with T1D also affect the development of other autoimmune disorders, so that understanding the genetic underpinnings of T1D will provide critical insights into the genetics and pathogenesis of those other diseases. For example, scientists have found that T1D and celiac disease share many risk genes and are now investigating potentially shared environmental triggers for T1D, celiac disease and other autoimmune disorders.[65]

The Potential Benefits and Savings from Future Advances

The NIH has provided support for basic research in T1D for 15 years, which suggests that the next decade may well see important, new therapeutic advances based on that research. We cannot know the precise nature and impact of those advances until they are broadly available. Recall that epidemiologists estimate that the average costs of T1D in 2020 will reach $38,600 per-patient, per-year, including $21,000 in medical-related costs and $17,600 in non-medical costs (Table 4, Panel 2, above). They further estimate that in 2020, 1.3 million Americans will suffer from diagnosed cases of T1D, at a total annual cost of $48 billion. (Table 4, Panel 1, above) If the NIH-supported research leads to advances by 2020 that reduce the incidence and severity of T1D by just 10 percent, the return on the SDP's original investments would be very large. The reduction in medical costs would come to $2.6 billion per-year, and the savings in other non-medical costs would total an additional $2.2 billion per-year. The total annual savings, therefore, would come to $4.8 billion. NIH funding for T1D research has totaled $1.89 billion over the last 15 years, and if we assume that the current support of $150 million per-year is maintained through 2020, the total support will come to $2.94 billion over 22 years. Under this scenario, the advances will produce an annual rate of return of 163 percent, year after year.

Moreover, if the spillovers from this research reduce the incidence and severity of T2D to even a modest degree, the savings will be much larger. Epidemiologists forecast that by 2020, 27.5 million Americans will suffer from diagnosed cases of T2D (Table 2, above), and each case

[63] World Health Organization (2011).

[64] Mayo Clinic (2011).

[65] National Institutes of Health (2010). "Special Statutory Funding Program for Type 1 Diabetes Research – Progress Report."

will involve average medical costs of $12,632, plus non-medical costs of $5,428 per-patient (Table 4, Panel 2, above). The total medical costs of diagnosed cases of T2D in 2020, therefore, will come to an estimated $347 billion in that year, and the total non-medical costs of those diagnosed in 2020 will come to an estimated $149 billion per-year. If the NIH-supported advances in T1D research lead to a 5 percent reduction in the incidence and severity of T2D, the reduction in medical costs would come to nearly $17.4 billion per-year, and the savings in other non-medical costs would come to some $7.5 billion. The total annual savings, therefore, would come to nearly $25 billion per-year, or more than 8.5 times the total projected NIH funding for the Special Diabetes Program over 22 years.

Such advances based on NIH research support also would produce large savings for Medicare and Medicaid. These two programs absorb 71 percent of the medical costs of diabetes (Figure 1, above). Based on the 2020 projections, the budgetary savings from a 10 percent reduction in the incidence and severity of T1D would come to nearly $1.85 billion per year or $18.5 billion over ten years. Similarly, the savings for Medicare and Medicaid from a 5 percent reduction in the incidence and severity of T2D, supported by spillovers from advances in T1D research, would come to more than $12.3 billion per-year or $123 billion over ten years. Under these scenarios, therefore, continued support for basic research in T1D could lead to savings for Medicare and Medicaid of nearly $14.2 billion in 2020 and every year thereafter, based on NIH investments of $2.94 billion over 22 years.

Table 8. Estimated Annual Costs of T1D and T1D, 2020, and Potential Annual Savings from Continued Scientific Advances

	Medical	Non-Medical	Total
T1D Costs, Per Diagnosed Case	$21,000	$17,600	$38,600
T1D Costs, All Diagnosed Cases	$26,000,000,000	$22,000,000,000	$48,000,000,000
T2D Costs, Per Diagnosed Case	$12,632	$5,428	$18,060
T2D Costs, All Diagnosed Cases	$347,000,000,000	$149,000,000,000	$496,000,000,000
Savings, 10% Reduction in T1D	$2,600,000,000	$2,200,000,000	$4,800,000,000
Medicare & Medicaid Savings	*$1,846,000,000*	--	*$1,846,000,000*
Savings, 5% Reduction in T2D	$17,350,000,000	$7,450,000,000	$24,800,000,000
Medicare & Medicaid Savings	*$12,318,500,000*	--	*$12,318,500,000*

Given the costs associated with diabetes today and for the foreseeable future, the advances which already have been achieved in its detection and treatment, based on NIH support, and the large economic and budgetary savings which could be achieved if NIH research support continues to produce advances, the economic case for continued NIH support for research in T1D is compelling.

VI. Conclusion

The fiscal pressures currently facing the federal government demand a dispassionate evaluation of the necessity and effectiveness of every program. This analysis has shown that the current NIH Special Diabetes Program of support for research into Type 1 diabetes is both necessary and highly cost-effective. This conclusion is reinforced by projections that the number of people with diagnosed diabetes will increase from 17.6 million in 2007 to 28.7 million in 2020.

These conditions impose very large costs on government and the economy. In 2007, Americans spent $128 billion treating diabetes, on top of an additional $65 billion in economic losses from reduced work and productivity associated with the condition. By 2020, experts estimate that these costs will reach $606 billion, including $410 billion in medical costs and $196 billion in other economic costs. Taxpayers are responsible for 71 percent of the medical costs, through the Medicare and Medicaid programs, or nearly $91 billion in 2007 and an estimated $291 billion by 2020.

The best hope for reducing the suffering from this disease and the enormous costs associated with it lies in sustained research and development into new ways of diagnosing and treating the disease. NIH support already has led to a number of breakthroughs that hold promise for better controlling the disease and its associated costs. For example, scientists recently identified a series of genes and gene regions involved in the development of T1D. These advances could soon lead to new tests to identify people at risk of developing T1D, new prevention strategies, and new treatment regimens based on a person's unique makeup. The support for basic research in TID has also funded the development of continuous glucose monitors which enable patients to maintain healthy levels of glucose and so reduce their likelihood of developing costly and potentially deadly complications. In addition, the program has produced substantial progress in islet transplants for T1D as well as the use of an "artificial pancreas," innovations which could also prove to be very important for people with T2D. The NIH funding also has led to the first large-scale screening of people at risk of developing T1D, providing new opportunities for early interventions which, based on other NIH-supported research, could delay the onset of the disease.

Not continuing the SDP also will lead to cutbacks in diabetes R&D by private pharmaceutical firms. Studies have found that a one percent increase in NIH-funded research leads to a 2.5 percent increase in private R&D spending, with a seven-year lag, as scientists working with or for private pharmaceutical companies build on the advances produced by the NIH-supported research. A reduction in NIH support for the SDP, therefore, would be expected over time to lead to even larger cutbacks in private R&D in this area.

We have further shown that if additional advances in the next seven years can lead to a 10 percent reduction in the incidence or severity of T1D, the savings in medical costs would top $2.6 billion per-year – including $1.7 billion in annual savings for Medicare and Medicaid – plus an additional $2.4 billion in, annual non-medical savings. And if spillovers from these advances lead to just a 5 percent reduction in the number of Americans with T2D, the annual savings in 2020 would be come to nearly $18 billion per-year in medical costs, including more than $11 billion per-year in Medicare and Medicaid savings, plus more than $7 billion per-year in other non-medical economic costs. The economic case for increasing NIH support for basic research in T1D, or at a minimum maintaining current levels of support, is clear and conclusive.

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