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Risk Analysis of Certifying Insulin-Taking Diabetic Private Pilots

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF TABLES (cont.)

I. INTRODUCTION

The purpose of this study is to develop estimates of the risk associated with the certification of insulin-taking diabetics as Class III student and private pilots.

Title 14, Part 67 - Medical Standards and Certification of the Code of Federal Regulations states that, to be eligible for a Class I, II, or III class medical certificate, a pilot must have "no established medical history of clinical diagnosis of diabetes mellitus that requires insulin or any other hypoglycemic drug for control."

Although procedures exist for appealing medical disqualifications for pilots' certificates directly to the FAA, no insulin-taking diabetic has ever been issued a pilot's license. The only diabetics currently flying aircraft are those who control their disease solely by diet.

Recently, a comprehensive review of medical certification criteria including those for diabetic pilots, has been undertaken by the FAA and the medical research establishment. This report complements that review. It is a study of the safety risks associated with the possible certification of insulin-taking diabetics for Class III student and private pilot certification. This information, in conjunction with expert medical opinion and analysis, is expected to be used by the Federal Air Surgeon in deciding whether to recommend changes in the regulations pertaining to certification of insulin-taking diabetic pilots.

The study includes an analysis of (1) the number of insulin-taking diabetics who would be interested in, as well as qualified to become, private pilots; (2) the expected number of accidents resulting from their certification; and (3) the comparable risk experienced by airmen in normal operation, e.g., night flying versus daytime flying. In addition, a review of literature regarding the risks of diabetic automobile drivers is presented.

Diabetes mellitus is a chronic disease characterized by disturbances of carbohydrate and lipid metabolism, and associated with the development of vascular and nervous system complications. Diabetes is, in effect, two diseases:

Type I - Juvenile onset of insulin dependent diabetes is generally contracted before the age of 30 (typically in early teen years), involves the destruction of pancreatic beta cells and almost always requires insulin therapy to avoid hyperglycemia - high blood glucose concentrations. Insulin dependent diabetics make up from 5 to 10 percent of all diabetics, approximately one-half a million U.S. citizens.

Type II - adult onset or non-insulin dependent diabetics is generally contracted later in life (about 40 percent of newly diagnosed cases of non-insulin dependent diabetics are over 65). It is characterized by a relative deficiency or impaired utilization of insulin which in most cases, is associated with obesity. Approximately 20 percent of the over five million adult-onset diabetics use insulin, 40 percent are controlled by oral hypoglycemic agents and the remainder rely on diet alone or do not take any measures to control their disease.

Counting both insulin dependent and non-insulin dependent diabetics, there are somewhat in excess of a million and a half insulin-taking diabetics in the United States, with the following age distribution:

Age	Percent of Insulin Taking Diabetics
0-16	5
17-44	26
45-64	36
65+	33
	100

Since its introduction in 1922, insulin has eliminated the widespread incidence of diabetic hyperglycemia. However, diabetics who are not careful in controlling their diet and/or drug regimen, are under significant physical or emotional stress, or (rarely) are metabolically instable and still subject to hyperglycemia. Symptoms include fatigue, nausea, blurred vision, and general malaise. Prolonged, severe hyperglycemia can lead to ketoacidosis and coma.

At the other extreme, insulin-taking diabetics (and to a lesser extent, oral-agent taking diabetics) are subject to hypoglycemia—low blood glucose concentrations. This can occur suddenly when carbohydrate intake does not balance insulin availability, such as when a meal is missed, there has been uncommon levels of exercise, or excessive amounts of insulin (or oral drugs) are taken. Hypoglycemia symptoms may include sweating, nervousness, rapid heart beat, mental confusion, and loss of consciousness. For most diabetics, early symptoms are clear and ingestion of a concentrated sweet will eliminate them in 10 to 15 minutes. In some diabetics, the early (mild) symptoms are missing or are not noticed, so that severe hypoglycemia episodes are experienced.

In addition to problems directly related to the control of the blood glucose levels, diabetes is associated with the accelerated development of macro and micro-vascular complications. These complications affect specific organs such as the eye (retinopathy) and kidney (nephropathy) or may be associated with increased frequency of coronary heart disease, stroke and peripheral vascular disease. It is estimated that of insulin-taking diabetics between 17 and 65 years old; 16 percent have cardiovascular disease; 18 percent have severe (proliferative) retinopathy; and 9 percent have persistent proteinuria (nephropathy).

The major findings of this analysis are:

- Approximately 500,000 insulin-taking diabetics could be eligible to become student or private pilots. Of these, 1,620 would be expected to eventually become Class III pilots if diabetic medical certification criteria are modified.

- The estimated safety risks for newly certified insulin-taking diabetic pilots would be about 30 percent greater than the ordinary risks associated with any general aviation pilot. The expected rate of fatalities for insulin-taking diabetic pilots is 4.8 per 100,000 pilot hours as compared to 3.7 for non-diabetic pilots.

- In the first 10 years after insulin-taking diabetic pilots begin to be certified, in-flight medical emergencies can be expected to result in an average of 0.6 fatalities per year. The ordinary risks associated with general aviation would be expected to result in an average of 1.9 additional fatalities per year. Therefore, the number of fatalities for insulin-taking diabetic pilots is expected to be about 2.5 per year on average during the first 10 years of certification.

- The added safety risks of certifying insulin-taking diabetic pilots is estimated to be about 20 percent of the added risks of flying at night versus during daylight hours and only 5 percent of the added risks of Instrument Flight Rules (IFR) flight versus Visual Flight Rules (VFR) flight for instrument rated pilots.

- Because there is considerable uncertainty surrounding the estimation of the safety risks for diabetic pilots, the actual accident rate experienced by this group could range from about the same accident rate as for other private pilots to twice their accident rate or more.

II. RISK ANALYSIS

The goal of this analysis is to estimate the expected number (and probability) of general aviation accidents that might occur if well controlled and otherwise healthy insulin-taking diabetics were permitted to obtain Class III private pilot certification. The analysis is divided into two segments: (1) estimation of the number of potential insulin-taking diabetic pilots; and (2) estimation of the safety risks per pilot and calculation of the expected number of accidents that would be associated with certification of insulin-taking diabetic pilots. A sensitivity analysis of parameters and assumptions is conducted to assess the range of possible outcomes, and a comparison to other safety risks is presented.

Number of Potential Insulin-Taking Diabetic Pilots

Included in the National Health Interview Survey (last conducted in 1981), are questions designed to ascertain the number of diagnosed diabetics by age groups. The following table summarizes these findings:

TABLE II.1
DIAGNOSED DIABETICS: 1981

Age	Number of Diabetics	Percent of Total Diabetics
0-19	93,000	1.6
20-44	854,000	15.1
45-64	2,523,000	44.6
65+	2,187,000	38.7
TOTAL	5,657,000	100.0

SOURCE: 1981 National Health Interview Survey

The current estimates of the total number of diagnosed diabetics by the National Diabetes Data Group of the National Institutes of Health is 5.8 million (Diabetes Data Group, Summary Statistics), and the percent of diabetics less than 17 years old has been estimated to be 1.4 percent (Diabetes Data, 1977, p. 11). Combining these data, the number of diabetics by age group is estimated to be:

TABLE II.2

DIAGNOSED DIABETICS: 1985

Age	Number of Diabetics	Percent of Total Diabetics
0-16	80,000	1.4
17-44	890,000	15.3
45-64	2,700,000	46.6
65+	2,130,000	36.7
TOTAL	5,800,000	100.0

The corresponding age distribution of student and private pilots (Class III) is as follows:

TABLE II.3

AGE DISTRIBUTION OF STUDENT AND PRIVATE PILOTS

Pilot Age	Percent of Active Pilot Population
Under 16	0.1
16-19	3.7
20-44	66.8
45-59	24.0
60+	5.6

SOURCE: General Aviation Pilot and Aircraft Activity Survey, 1983.

It is clear that the overall diabetic population is considerably older than active student and private pilots. Since diabetics above the age of 65 are not likely to become new Class III pilots if the regulations were changed, and there is an insignificant number of young, teenage pilots, estimates of potential diabetic pilots will be restricted to those between the ages of 17 and 64. Furthermore, this analysis will be limited to insulin-taking diabetics.

Based on a sample of 756 diabetics from the National Health and Nutrition Exam Survey (1981) (Diabetes in America, 1985, pp. XXIV-2), the percentage of insulin-taking diabetics in each age group is as follows:

TABLE II.4

PERCENT OF DIABETICS USING INSULIN

Age	Percent Using Insulin
12-34	46
35-44	47
45-54	22
55-64	21
65-74	24

If it is assumed that all diabetics under the age of 20 are insulin dependent, then, an estimate of the age distribution of insulin-taking diabetics is as follows:

TABLE II.5

INSULIN-TAKING DIABETICS

Age	Insulin-Taking Diabetics	Percent of Total Insulin-Taking Diabetics
Under 17	80,000	5.0
17-44	410,000	25.5
45-64	580,000	36.0
65+	540,000	33.5
TOTAL	1,610,000	100.0
17-64	990,000	

Furthermore, evidence from several sources (Melton, et al., 1983; Laakso, 1985; National Diabetes Data Group, 1982) indicate that the proportion of insulin dependent diabetics (Type I) is between five to ten percent of the total of all diabetics. Insulin-taking, non-insulin dependent diabetics (Type II) account for the rest of insulin-taking diabetics. This distinction is important because insulin-taking Type II and insulin-dependent diabetics differ on a number of health-related characteristics.

If it is assumed that eight percent of diabetics are insulin-dependent, then 465,000 diabetics can be classified as insulin-dependent. Of these, 80,000 are estimated to be under the age of 17, leaving 385,000 insulin-dependent diabetics over the age of 17. Because the average life span of insulin-dependent diabetics is less than for the non-diabetic population (Krolewski, 1985) and insulin was introduced and widely used only about 60 years ago, it is assumed that an insignificant proportion of insulin-dependent diabetics are over 65 years of age. Insulin-dependent diabetics, therefore, constitute about 39 percent of the 990,000 insulin-taking diabetics between the ages of 17 and 65.

Disqualifying Complications of Diabetes

Many insulin-taking diabetics would not be expected to pass a medical examination for a Class III pilot's certificate, even if the disqualification for diabetes were to be removed. This is because many diabetics have complications which are also disqualifying for pilot certification. Chronic diabetic complications which affect a significant number of people in the 17 to 65 age ranges include: retinopathy, nephropathy, and cardiovascular disease. Another common chronic complication of diabetes, neuropathy, was not considered to be disqualifying for pilot certification unless symptoms were severe and, therefore, was not included in the analysis.

Diabetic Retinopathy is one of the leading causes of blindness in the United States. It is characterized by: (1) leakage of fluid from the retinal capillaries, (2) microaneurysms and occlusion of the retinal vessels; and (3) proliferation of newly formed blood vessel along the inner surface of the retina (U.S. Department of Heath and Human Services, 1980). Retinopathy is more common in Type I diabetics than in Type II diabetics. For both types, however, it is strongly related to the time since onset of diabetic symptoms. A recent comprehensive population-based study of diabetic retinopathy (Klein, 1984) on 996 insulin-dependent and 1,370 non-insulin-dependent diabetics showed overall prevalence of proliferative retinopathy to be 14.1 percent for insulin-taking, Type II diabetics and 26.6 percent for Type I diabetics. These data generally agree with other studies which report from 8 percent to 38 percent prevalence of severe retinopathy (Frier, 1980; Krolewski, 1985).

Using Klein (1984), the distribution of proliferative retinopathy in insulin-taking diabetics who are candidates for a Class III pilot's certificate is calculated as follows:

TABLE II.6

INSULIN-TAKING DIABETICS WITH PROLIFERATIVE RETINOPATHY

	Number of Diabetics	Percent with Proliferative Retinopathy	Number with Proliferative Retinopathy
Type I	385,000	26.6	102,000
Type II	605,000	14.1	85,000
TOTAL	990,000	18.9	187,000

Thus, it is estimated that 187,000 insulin-taking diabetics would be disqualified on the basis of this visual disorder.

Another diabetic complication that would probably cause disqualification or otherwise prevent a person from becoming a pilot is nephropathy. Nephropathy, as evidenced by persistent proteinuria, is a serious complication of insulin-dependent diabetes (and to a lesser extent for Type II diabetics). From 35 to 50 percent of Type I diabetics will eventually develop persistent proteinuria during the course of the disease (Knowles, 1971; Krolewski, 1985). The risks of developing proteinuria increase rapidly between the fifth and fifteenth years of Type I diabetes to a peak incidence of 2.5 percent per year. Nephropathy inevitably progresses from initial symptoms to end stage renal failure with half of all Type I diabetics with persistent proteinuria reaching this stage in approximately 10 years after onset of persistent proteinuria. Nephropathy is also often associated with other microvascular and macrovascular complications and accounts for about one-third to two-fifths of the deaths of Type I diabetics.

Estimates of the prevalence of persistent proteinuria range from 2 percent to 10 percent of Type II diabetics, and from 6.7 percent to 20 percent of Type I diabetics (Marks and Krall, 1971; Warram, 1985; Pell and D'Alonzo, 1967). Prevalence of nephropathy is considerably lower than cumulative incidence because of the high rate of early mortality among diabetics with this complication. The prevalence rates used in this study correspond to estimates developed by Pell and D'Alonzo, as follows. (Their insulin users above 50 units per day were assumed to be Type I, below 50 units per day were assumed to be Type II):

TABLE II.7
PERCENT OF INSULIN-TAKING DIABETICS
WITH PERSISTENT PROTEINURIA

Type	Prevalence
Type I	12.5%
Type II	6.7%

Using these data, the number of insulin-taking diabetics between 17 and 64 years of age with nephropathy as indicated by persistent proteinuria is estimated as follows:

TABLE II.8
INSULIN-TAKING DIABETICS
WITH PERSISTENT PROTEINURIA

	Number of Diabetics	Percent with Proteinuria	Number with Proteinuria
Type I	385,000	12.5	48,000
Type II	605,000	6.7	41,000
TOTAL	990,000	9.0	89,000

Thus, it is estimated that 89,000 insulin-taking diabetics would be disqualified on this basis of persistent proteinuria (nephropathy).

Diabetes mellitus is associated with vascular diseases of the large blood vessels, atherosclerosis, as well as diseases of the capillaries of the eye and kidney. Large artery disease in diabetics is clinically expressed as myocardial infarction, stroke, and intermittent claudication. These complications occur in middle-age diabetics with high frequency, even when the major symptoms of carbohydrate imbalance have not been experienced. In diabetes, cardiovascular problems progress more rapidly and are seen at earlier ages than in non-diabetics. However, there is little or no evidence that the arterial lesions in diabetics are different from those in the non-diabetic population. In fact, cardiovascular risk factors for diabetics and the general population are similar: cigarette smoking, elevated concentrations of cholesterol, and hypertension. For diabetic women, however, the risks of cardiovascular disease are much closer to the risks for diabetic men than is true for the non-diabetic population (U.S. Department of Health and Human Services, 1980; Thomas and Kannel, 1983).

The prevalence of cardiovascular diseases among diabetics is approximately twice the rate for non-diabetics (Thomas and Kannel, 1983). Prevalence estimates for cardiovascular diseases range from 25 percent to as high as 42 percent of diabetics (Diabetes Data, 1977). These figures pertain mainly to Type II diabetics who are, on average, older than prospective insulin-taking diabetic pilots. Since prevalence of heart disease increases rapidly with age, it is likely that a considerably lower proportion of under 65 year old diabetics have heart conditions than is reported in the literature for all diabetics.

To estimate the proportion of prospective diabetic pilots who have cardiovascular diseases, the age specific general population prevalence of chronic heart conditions (Statistical Abstract of the United States, 1985) is employed as follows. (Note that general population prevalence rates are multiplied by a factor of two to account for the higher prevalence among diabetics).

TABLE II.9

PERCENT OF INSULIN-TAKING DIABETICS WITH CHRONIC HEART CONDITIONS (CHC)

Age	Number of Diabetics)	General Population Prevalence of CHC X 2	Number of Diabetics With CHC
17-44	410,000	7.5%	31,000
45-64	580,000	24.5%	142,000
TOTAL	990,000	17.5%	173,000

Thus, it is estimated that 173,000 insulin-taking diabetics would not be qualified for private pilot certification due to chronic heart conditions.

The number of potential diabetic pilots should be reduced by the proportion which has one or more complication. Unfortunately, no estimates of co-morbidity among insulin-taking diabetics are available, although general sources (Krolewski, 1985; Warram, 1985) indicate that the prevalence of diabetic complications increases with age and duration of the disease, and that persons with nephropathy are also likely to suffer from coronary and visual complications.

To calculate the proportion of diabetics without complications, two alternative assumptions are employed (the true prevalence is probably between the two):

1. The probability of having any complication is independent of the probability of having the other complications.
2. All diabetics with nephropathy have cardiovascular disease and proliferative retinopathy; for diabetics without nephropathy, the chances of having heart disease and retinopathy are not related.

Estimates of the number of insulin-taking diabetics between 17 and 65 years old without complications is calculated to be:

TABLE II.10

PREVALENCE OF DIABETIC COMPLICATION IN INSULIN-TAKING DIABETICS, AGE 17-64

	Percent of Diabetics Without Complications	Number of Diabetics Without Complications
Assumption 1	60.9	603,000
Assumption 2	75.0	742,000
AVERAGE	68.0	673,000

The average of these two assumptions, i.e., 68 percent and 673,000, is used as the best estimate of the number and proportion of insulin-taking diabetics without disqualifying complications.

Persistent hyperglycemia or poor diabetic control, is assumed to be an additional condition that will be disqualifying for pilot certification. The proportion of diabetics who do not maintain adequate diabetic control can be inferred from several sources (Krolewski, 1985, Klein, 1984). The proportion that would fail an aviation medical exam because of hyperglycemia cannot be established until standards are developed. However, it is clear that a substantial proportion—estimated between 14 percent and 54 percent of insulin-dependent diabetics and 20 percent to 59 percent of insulin-taking Type II diabetics—do not have normal blood glucose and urine tests at visits to the clinic or hospital. Because glycemic control is thought to be related to the probability of contracting microvascular complications, a substantial proportion of diabetics with poor control may also have contracted one or more of the disqualifying complications. Therefore, it is assumed that a relatively low percentage, 25 percent or 168,000 insulin-taking diabetics between the ages of 17 and 65, are not affected by disqualifying diabetic complications but are unfit to be Class III pilots because of poor diabetic control.

Thus, the number of potential insulin-taking diabetic pilots is estimated to be:

$$673{,}000 - 168{,}000 = 505{,}000.$$

It is evident that not all eligible diabetics will desire to become student or private airplane pilots. The proportion who will is probably no higher than the proportion of the general population who currently hold Class III pilot's certificates. Thus, it is assumed that the proportion of otherwise healthy, insulin-taking diabetics between the ages of 17 and 65 who will eventually become student or private pilots is equal to the proportion of Class III pilots in the general population.

The number of active student and private pilots in 1982 is estimated to be 470,000 (U.S. Civil Airmen Statistics, 1984). The general population of the U.S. between 17 and 65 is 148,195,000 (Statistical Abstract of the United States, 1985). Therefore, the proportion of private pilots in the general population is 470,000/148,195,000 = .32 percent.[1]

[1]Ideally, one should calculate the percent of pilots based on an estimate of the general population excluding those that would be disqualified due to heart, eye, and kidney diseases. However, the proportion of flying age people who have those diseases is small. Furthermore, the effect of excluding these people would be offset if diabetics with other disqualifying medical conditions were excluded from the diabetic population.

Finally, the expected number of prospective insulin-taking diabetic pilots is estimated to be approximately:

$$.0032 \times 505{,}000 = 1{,}620 \text{ pilots}$$

Safety Risks for Insulin-Taking Diabetic Pilots

Insulin-taking diabetic pilots are subject to safety risks similar to those of any student or private pilot, but, in addition, they face risks associated with their particular disease. These include:

1. hypoglycemic reactions;
2. hyperglycemia, ketoacidosis and diabetic coma; and
3. cardiovascular events.

Hypoglycemic Reactions

Hypoglycemia is the most common metabolic emergency in insulin-treated diabetics (Gale, 1980). It is the most serious medically-related safety threat to insulin-taking diabetic pilots. Hypoglycemia is caused by a relative insulin excess, which occurs in diabetics when: (1) the amount of insulin (or to a lesser degree oral hypoglycemic agents) is increased or maintained at too high a level; (2) carbohydrate intake is inadequate (such as when a meal is missed); or (3) peripheral glucose uptake is accelerated (such as after strenuous exercise). Hypoglycemic symptoms develop in most diabetics as blood glucose levels drop to levels in the range of 36-45 mg/dl, but may also occur with drops of 100 mg/dl or more from higher blood glucose concentrations. Symptoms of hypoglycemia generally begin with certain early warning signs, may progress to diminished mental function, and eventually to profound coma or convulsions (Sussman, 1962). The first symptoms—rapid heart beat, perspiration, light-headedness, and anxiety—provide a clear signal to most diabetics to take corrective action (usually ingestion of a concentrated carbohydrate). Thereafter, blood glucose levels generally return to normal levels and symptoms disappear within 10 to 15 minutes, or less. However, in a small percentage of diabetics, the early symptoms are not present or are masked by neuropathy, so that the diabetic progresses directly into a phase characterized by decreased mental function. Symptoms include lethargy, mental confusion, decreased conversational ability, and diminished short-term memory. Eventually, the faculties necessary to take corrective action may be lost, so that the aid of another person is necessary to prevent coma or convulsions. In a small percentage of diabetics, blood glucose levels may increase spontaneously without intervention. This, "rebound hyperglycemic reaction" is the result of the release of epinephrine in response to low blood glucose concentrations.

Mild hypoglycemia is a safety hazard to diabetic pilots if: (1) the symptoms occur at a critical phase of flight or when other safety problems are occurring; or (2) if a concentrated carbohydrate is not available within the airplane. Severe hypoglycemia—when the assistance of another person is needed to take corrective action--poses a very high risk of an accident. Very little data are available on the incidence of mild hypoglycemic reactions. Two French studies (Goldgewight, 1983; Basderant, 1982) estimate the incidence of approximately one per week for well controlled insulin-taking diabetics who are seen at clinics or hospitals. A diabetologist at the Joslin Clinic estimated that his patients have from one to two mild reactions per week (Vignati, 1985).

The incidence of severe hypoglycemia is measured by admissions to hospital emergency rooms, or has been reported in several specific studies of hypoglycemia (Goldgewight, 1983; Basderant, 1982; Vignati, 1985; Casparie, 1985; Potter, 1982). Estimates of the incidence of severe hypoglycemia ranges from 80 per 1,000 patient years to 500 per 1,000 patient years (averaging 260 reactions per 1,000 patient years). Many researchers state that they feel the incidence of both mild and severe hypoglycemia is understated due to underreporting of incidents. On the other hand, several of the studies of hypoglycemia are based on select groups of patients who are trying to maintain very tight control of their disease. Using these data would tend to overemphasize the extent of hypoglycemic incidence among the entire population of diabetics.

To calculate the expected number of hypoglycemic reactions per diabetic per year while in flight, it is necessary to estimate the average number of hours flown by student and private pilots. The average number of hours flown is estimated from data on: (1) the total number of general aviation hours flown in the United States civil air fleet, except those flown under scheduled air transportation or by large aircraft commercial operators (Census of U.S. Civil Aircraft, 1984); and (2) the number of active pilots (U.S. Civil Airmen Statistics, 1984).

average hours flown in general aviation =
total GA aircraft hours flown/number of active pilots =
35,200,000/722,400 =
48.7 hours per pilot per year[2]

Then, the expected incidence of hypoglycemia in flight =
E (number of hypoglycemic reactions) *
(average hours flown per year/number of hours in a year) =
E (hypoglycemic reactions * (48.7/8,760)

And, if it is assumed that an insulin-taking diabetic will average 50 mild hypoglycemic reactions per year, and 260/1,000 = .26 severe hypoglycemic reactions per year, then, the expected number of hypoglycemic reactions in flight per diabetic pilot during the course of a year is estimated to be:

TABLE II.11
HYPOGLYCEMIC REACTIONS

Type	Number of Reactions Per Pilot Per Year	Expected Number of Reactions In Flight Per Pilot Per Year
Mild	50	0.28
Severe	0.26	0.0014

There is no quantitative information available from which to estimate the likelihood that a hypoglycemic reaction occurring in flight will cause an accident. For purposes of this study, it was assumed that if a mild hypoglycemic reaction takes place during a flight a student or private pilot would find himself in a situation that was ten times more dangerous than that faced by pilots under normal circumstances. A severe hypoglycemic reaction in which the diabetic would be unconscious or in need of assistance from another person to recover, is assumed to lead to an accident in 80 percent of such situations (another pilot would take over in the case where an accident was avoided).

[2]Student and private pilots probably fly somewhat fewer GA hours on average than commercial and air transport pilots, but the exact breakdown is not known.

Since there have been in excess of 1,800 general aviation accidents to Class III pilots annually in recent years, (FAA Accident/Incident Data System, 1985) the chances of a student or private pilot being involved in an accident in a year are about 1 in 260 (.38 percent per year). Then, the probability of an accident in flight due to incapacitation resulting from a mild hypoglycemic reaction is estimated to be:

probability of an accident per hour due to mild hypoglycemia =
10 * normal accident rate per year/(number of flight hours per year) =
10 x (.0038)/48.7 = .0008

The expected number of general aviation accidents occurring to all insulin-taking student and private pilots due to hypoglycemia is calculated as the expected number of reactions inflight, times the probability of an accident given a reaction, times the total number of insulin-taking diabetic pilots. Thus,

TABLE II.12

HYPOGLYCEMIA-CAUSED ACCIDENTS

Type	Expected Number of Accidents Per Pilot Per Year	Total Expected Number of Accidents Per Year
Mild	.00022	0.4
Severe	.0011	1.8
TOTAL	.0013	2.2

Hyperglycemia, Ketoacidosis, and Coma

Hyperglycemia, defined as an excessive concentration of blood glucose, at times effects all diabetics whether they control their disease by use of insulin, hypoglycemic agents, or by diet alone. Data from admissions to clinics indicate that a relatively high percentage of diabetics have high blood glucose levels at the time of examination, for example:

TABLE II.13

PERCENT OF DIABETICS WITH HIGH BLOOD GLUCOSE TESTS AT THE TIME OF EXAMINATION

Type	Percent with Blood Glucose Greater than 200 Mg/Dl
insulin-dependent	39
non-insulin-dependent	30

SOURCE: Krolewski, 1985

In the long-term, persistently high levels of blood glucose are thought to be associated with increased chances of developing diabetic complications. Very high glucose concentrations caused by non-adherence to diet and drug regime and/or stress from infection or disease, places a diabetic at risk of developing ketoacidosis. This serious condition (10 percent of hospital admissions for ketoacidosis result in mortality) is almost always preventable since it develops slowly over a period of hours or days and is accompanied by easily recognizable symptoms (Faich, 1983). Most cases of ketoacidosis are among previously diagnosed insulin-taking diabetics although about 20 percent or more occur concurrently with the diagnosis of diabetics. Young insulin-dependent diabetics have the highest incidence, probably due to their high rates of poor control. Infections are the primary precipitant of ketoacidosis, accounting for over 40 percent of all cases. Coma is present in over 10 percent of ketoacidosis admissions.

Symptoms of hyperglycemia include glycosuria, frequent urination, thirst, tiredness, malaise, mental obtundation, nausea (Benson, 1979), and blurred vision (Vignati, 1985). With ketoacidosis, the following symptoms are added: ketonuria, stupor, hypothermia, vomiting, and dehydration.

The more serious symptoms are associated with higher concentrations of blood glucose. However, no data are available on the incidence of specific symptoms, such as blurred vision, which would detract from piloting performance. Several studies (Melton, 1975; Knowles, 1965; Gottlieb, 1980) indicate that a fairly high percentage of Type I diabetics (e.g., 35 percent after 20 years duration) will eventually be hospitalized for ketoacidosis, while only a small percent (e.g., 5 percent) of non-insulin-dependent diabetics report one or more admissions for ketoacidosis. Annual hospital admission rates for ketoacidosis range from 1.3 percent of Type I diabetics (Johnson, 1980) to less than 0.5 percent of all diabetics (Faich, 1983). Self-reported coma in juvenile diabetics has been reported by about 2 percent of patients per year (Krolewski, 1985).

Because, as reported in one study (Krolewski, 1985), over 35 percent of insulin-dependent diabetics had trace or significant ketonuria (a measure of diabetic acidosis) at the time of examination, it can safely be assumed that diabetic acidosis, accompanied by some of the symptoms listed above, is more common than implied by hospital admissions rates. On the other hand, approximately 30 percent of patients with one or more admissions for ketoacidosis (Biegelman, 1971) have experienced multiple hospital admissions for ketoacidosis and would presumably be excluded from the pool of potential diabetic pilots due to a history of unsatisfactory control of their disease. For these reasons, it is extremely difficult to estimate the impact that hyperglycemia would have on pilot accident rates. Ketoacidosis is extremely serious, but rare; other symptoms of high blood glucose are much more common, but if mild, may be inconsequential and, if more severe, should give clear warning to diabetic pilots to avoid flight.

For purposes of this study, the safety consequences of hyperglycemia will be calculated as follows:

TABLE II.14

ASSUMED INCIDENCE OF HYPERGLYCEMIA IN INSULIN-TAKING DIABETIC PILOTS

Type	Per diabetic Per Year	Prob. Accident Given Event Occurs In Flight
Ketoacidosis	.01	0.8
Other symptoms which might affect pilot performance	0.2	10 x normal accident rate (.0008)

The expected number of hyperglycemic episodes that would occur to insulin-taking diabetic pilots while inflight is estimated to be:

E (hyperglycemic episodes in flight) = incidence * (# hours in flight/# hours per year)

This equals .0008 for ketoacidosis and .0018 for other symptoms. The expected number of accidents due to symptoms of hyperglycemia are then:

E (accidents) = E (episodes) * p (accident/episode) * # of pilots

Thus,

TABLE II.15

HYPERGLYCEMIA CAUSED ACCIDENTS

Type	Expected Number of Accidents Per Pilot Per Year	Total Expected Number of Accidents Per Year
Ketoacidosis	.00006	0.1
Other	*	*
TOTAL	.00006	0.1

*negligible

Cardiovascular Disease

Diabetics with insulin-dependent and non-insulin-dependent forms of the disease are both at increased risk for coronary heart disease, stroke, and peripheral vascular disease (Podell and Stewart, 1985). Of these, the major medical safety risk for diabetic pilots is sudden heart attack (myocardial infarction) and stroke (cardiovascular accident). Peripheral vascular disease, generally expressed as lower leg pain (intermittent claudication), are probably not a significant aviation safety risk.

Heart attacks occur in the general population at a rate of nearly 1.5 million per year, while the incidence of stroke is about 500,000 per year, (American Heart Association, 1985). Many of these strike the elderly as is demonstrated in the following table derived from data compiled by the Framingham Heart Study (Kannel and Gordon, 1974).

TABLE II.16

INCIDENCE OF MYOCARDIAL INFARCTION (MI) AND CEREBROVASCULAR ACCIDENT (CVA) IN DIABETIC AND NON-DIABETIC MEN WITH NO PREVIOUS HISTORY OF HEART DISEASE OR STROKE

Age	Annual Incidence of MI Per Diabetic	Annual Incidence of MI Per Non-Diabetic	Annual Incidence of CVA Per Diabetic	Annual Incidence of CVA per Non-Diabetic
45-54	.0075	.0040	.0096	.0018
55-64	.0108	.0088	.0055	.0034
65-74	.0189	.0094	.0110	.0076

These data imply that the incidence of myocardial infarction (MI) for non-elderly diabetics (45-64) is about one percent per year and the incidence of stroke is almost .75 percent per year. The rates of MIs and CVAs in diabetics and non-diabetics below age 45 are not calculated, but can be assumed to be negligible. Based on the age distributions of insulin-taking diabetics (TABLE II.5) and of student and private pilots (TABLE II.3), it is probable that less than 50 percent of newly registered diabetic pilots would be over 45 years of age.

Thus, the risks of a heart attack and stroke to an insulin-taking diabetic can be estimated as follows (assuming that most new diabetic pilots would be males):

E (# of MI and CVA to insulin-taking diabetic pilots) =
(incidence of MI plus CVA to diabetics, ages 45-64) *
(percent of insulin-taking diabetic pilots older than 45) =
(.01 + .0075) x .5 = .0088 heart attacks and strokes per diabetic pilot per year

Since diabetics have about twice the incidence of cardiovascular disease as the non-diabetic population (Podell and Stewart, 1985), the excess risk of heart attack and stroke for diabetic pilots is only about half of this estimate, or .0044 heart attacks and strokes per diabetic pilot per year.

The expected annual number of incidents per insulin-taking diabetic pilot that can be expected to occur in flight is then:

expected # of incidents * (# hours in flight/total hours per year) =
.0044 * 47.8/8,760 = .000024

If it is assumed that the chance of an accident given a heart attack in flight is 80 percent, then the number of accidents due to coronary heart incidents among all insulin-taking diabetic pilots can be estimated to be:

E (incidents in flight) * prob. (accident/incident) * # of pilots =
.000024 * .8 * 1,620 = .03 accidents per year

Thus, the overall additional risk to prospective insulin diabetic pilots is estimated as follows:

TABLE II.17

ESTIMATED MEDICAL SAFETY RISKS TO INSULIN-TAKING DIABETIC PILOTS

Risk Category	Expected Accidents Per 100,000 Pilot Hours	Expected # of Accidents Per Year for 1,620 Diabetic Pilots
Hypoglycemia	2.84	2.2
Hyperglemia	.12	0.1
Cardiovascular	.04	0.03
TOTAL	3.00	2.33

The normal risks assumed by diabetics as well as non-diabetic Class III pilots is one accident in about 260 pilot years (7.9 per 100,000 pilot hours), or about 3.4 times the added risk due to diabetes.

Since 1980, the number of fatalities to student and private pilots in general aviation has averaged about 660 per year, or about 37 percent of the number of accidents in this type of flying. If this ratio were to remain unchanged, then the annual number of fatalities to insulin-taking diabetic pilots is estimated to be as follows:

TABLE II.18

ESTIMATED FATALITIES TO INSULIN-TAKING DIABETIC PILOTS

Cause	Expected # of Fatalities Per 100,000 Pilot Hours	Expected # of Fatalities for 1,620 Diabetic Pilots Per Year
Medical incapacitation related to diabetes	1.1	0.9
Ordinary risks of piloting	3.7	2.9
TOTAL	4.8	3.8

Not all eligible insulin-taking diabetic pilots would be expected to become certified immediately if the regulations were changed. A reasonable schedule for new certifications might be as follows:

TABLE II.19

EXPECTED CERTIFICATIONS OF INSULIN-TAKING DIABETIC PILOTS

Year	Expected Number of Certifications
1	400
2	300
3	200
4+	100

Thus, after 10 years almost all (1,600) of the insulin-taking diabetic pilots expected to eventually become certified will have received their pilot's licenses. The expected number of accidents and fatalities per year during this initial 10-year period is estimated to be as follows:

TABLE II.20

INITIAL 10-YEAR SAFETY RISK FOR INSULIN-TAKING DIABETIC PILOTS

Cause	Initial 10-Year Annual Average Expected # of Fatalities to Insulin-Taking Diabetic Pilots
Diabetes-related medical incapacitation	0.6
Ordinary risks of piloting	1.9
TOTAL	2.5

Sensitivity Analysis

The analysis of the safety risks associated with certifying insulin-taking diabetic pilots relies on the estimation of many data values, about which there is considerable uncertainty. The reasons for these uncertainties include:

1. Variation in the definition of terms used in different studies, e.g., severe hypoglycemia or chronic heart disease;

2. Differences in the populations studied from which parameter estimates were derived, e.g., patients at French diabetic clinics versus residents of Rochester, Minnesota.

3. Measurement of a different, but similar characteristic from which inferences had to be made, e.g., the incidence of self-reported diabetic coma versus hospital admissions for ketoacidosis.

4. Variation in the recentness of research findings in cases where there were trends in incidence or prevalence rates, e.g., the proportion of diabetics taking insulin or oral hypoglycemic agents.

5. Small sample sizes for study populations, which may lead to unreliable or nonrepeatable results.

6. Lack of relevant research findings because available data have not been analyzed, e.g., the proportion of diabetics that have more than one debilitating (disqualifying) medical condition related to diabetes.

7. Lack of relevant research findings or data because the situation has not occurred with sufficient frequency to develop data, e.g., the likelihood of an airplane accident due to mild hypoglycemic reactions in diabetic pilots.

Because there are so many variables that have uncertain values, it is important to identify where errors might make significant differences in the final estimates of safety risks. The following table shows how variation in each of the important variable impacts the estimate of accidents related to certification of insulin-taking diabetic pilots.

TABLE II.21

EXPECTED CHANGE IN ESTIMATED ACCIDENTS GIVEN VARIATION IN ASSUMPTIONS

Data Item	Value Used	Range	% Change in Expected Number of Accidents
Total # of Diabetics	5.8 million	± 10%	± 10%
% Using Insulin	28%	26% - 31%	-6%, +9%
% Insulin Dependent	8%	5% - 10%	± 2%
% With Proliferative Retinopathy	18.9%	8% - 38%	+12%, -10%
% With Cardiovascular Disease	17.5%	10% - 25%	± 6%
% With Proteinuria	9%	4% - 14%	± 1%
% Under Poor Control	25%	15% - 60%	+ 13%, -52%
Incidence of Hypoglycemia			
Mild	50/person-yr.	25 - 100	-9%, +18%
Severe	.26/person-yr.	.08 - 0.5	-47%, +71%
Incidence of ketoacidosis	1%	0.5% - 1.3%	-2%, +4%
Probability of an accident given:			
Mild Hypoglycemic Reaction	10 x normal accident rate	2x - 100x	-14%, +160%
Severe hypoglycemic Reaction	0.8	0.5 - 1.0	-29%, +19%
Ketoacidosis	10 x normal accident rate	2x - 100x	-2%, +26%
Coronary heart attack	0.8	0.5 - 1.0	± .3%

Comparison with Other Aviation Safety Risks

The added risks of accidents due to the certification of insulin-using diabetics as student and private pilots is estimated to lead to 3.8 general aviation fatalities per year among the 1,620 new pilots. Of these, 0.9 fatalities would be due to diabetic medical conditions and 2.9 fatalities would be due to the ordinary risks associated with flying. Thus, the safety risks for prospective insulin-taking diabetic pilots are estimated to be about 30 percent higher than the risks for non-diabetic private pilots.

How do these added risks compare to risks taken by currently certified pilots? Based on FAA accident statistics (1980-1983) for pilots with specific medical conditions, the Class I, II, and III diet-controlled diabetic pilots currently active have an accident rate per pilot year that averaged approximately 38 percent higher than the overall pilot accident rate (FAA Accident Incident Data, 1985). Although diet-controlled diabetics are much less likely than insulin-taking diabetics to experience hypoglycemic reactions (the major diabetic medically-related safety risk) nevertheless, they have experienced a measurably higher rate of accidents. Many factors could account for this higher accident rate, including variation in the age distribution of diabetic versus other pilots, or differences in the types of flying undertaken.

To illustrate how these other factors could be important influences on aviation safety risks, it is noted that Class III pilots with monocular vision have an accident rate per pilot which is 80 percent of the average for all Class III pilots (Dille and, Booze, 1983). Presumably, the lower accident rate for pilots who are blind in one eye could only be explained if these pilots have restricted their flying to relatively safe situations, e.g., favorable weather conditions.

Variation in pilot age, as shown in the following table, appears to have a non-trivial potential for impacting student and private pilot accident rates (FAA Accident Incident Data Summary, 1985; General Aviation Pilot and Aircraft Activity Survey, 1983). The difference in accident rates per active Class III pilot between 16-24 years old and 50-54 year old is 82 percent.

TABLE II.22

AVERAGE 1980-1984 ACCIDENT RATE FOR CLASS III PILOTS IN GENERAL AVIATION BY AGE GROUP

Age Range	Total Number of Accidents	Annual Rate of Accidents Per Active Pilot
16-19	207	.28%
20-24	635	.28%
25-29	882	.31%
30-34	1,069	.35%
35-39	1,045	.36%
40-44	918	.40%
45-49	862	.45%
50-54	833	.51%
55-59	593	.47%
60+	532	.48%

The variation in safety risks associated with night flying and flying in adverse environmental conditions are even more pronounced. The additional risks private pilots accept when they decide to fly at night is summarized below. The exposure estimate of 4.9 percent for private pilot night flying is based on an unpublished FAA document: Graham, W. The Study of General Aviation Safety, February 7, 1980.

TABLE II.23

NIGHT VERSUS DAYTIME ACCIDENT RISKS FOR CLASS III PILOTS

Average student and private pilot accidents, 1980-1983	1,800
Total expected Class III night accidents (based on 4.9 percent night exposure rate)	88
Average actual Class II night accidents	215

SOURCE: FAA Accident Incident Data Base

Thus, for private pilots, night flying constitutes a risk of two and one-half times that of day flying. In comparison, the additional safety risks associated with certification of insulin-taking diabetics was estimated to be about 30 percent higher than normal risks, which is only about 20 percent the added accident risk of night flying.

Accident rates for Instrument Flight Rules (IFR) and Visual Flight Rules (VFR) flying also vary considerably, as can be seen in the following table (Graham, 1981):

TABLE II.24

ACCIDENT RATES FOR INSTRUMENT-RATED AND NON-INSTRUMENT-RATED PILOTS

	VFR-only Pilots	IFR-rated Pilots
VFR flight	1 accident per 61,900 hours	1 accident per 94,800 hours
IFR flight	1 accident per 1,400 hours	1 accident per 12,200 hours

Thus, for instrument-rated pilots, flying under IFR conditions is about eight times as dangerous as flying under VFR conditions. Flying in IFR conditions is obviously even more dangerous for non-instrument rated pilots. By comparison, the added safety risks of IFR flight for instrument-rated pilots is over 20 times more dangerous than the added risk of insulin-taking diabetic pilots relative to all Class III pilots in general aviation.

III. REVIEW OF SAFETY EXPERIENCE OF DIABETIC DRIVERS

This section reviews the safety record of diabetic automobile drivers as analyzed in the literature. The studies, summarized in Table III.1, indicate that the accident rate for diabetic automobile drivers ranges from about the same to 1.8 times the accident rate for non-diabetic drivers. The three studies conducted in the United States found that diabetics had auto accident rates that were higher than non-diabetics. Two of these studies showed the differences to be statistically significant. The foreign studies generally showed little or no differences in accident rates between diabetic and non-diabetic drivers.

The usefulness of these studies to gain insight into the accident rate that might be expected for insulin-taking diabetic pilots is impaired because the automobile studies were conducted on groups of diabetics who differed in significant ways from prospective diabetic pilots.

Many of the studies did not distinguish between insulin-taking and non-insulin-taking diabetics (over 70 percent of all diabetics do not take insulin), and did not adequately differentiate between older and younger drivers (although most adjusted results for age differences). Thus, the diabetic populations used in these studies were generally older and less likely to use insulin than prospective pilots. In addition, although some studies examined the driving records of all diabetics in the population, most studies based their results on only those diabetics who were issued medically restricted licenses. Medically restricted diabetic drivers represent only a small percentage of all diabetics. They either declared to motor vehicle authorities that diabetes might interfere with their driving proficiency or were discovered to be diabetic as a result of a traffic violation or an accident. Therefore, these studies may be biased because the safety records of diabetics who did not report their disease were not examined.

TABLE III.1

STUDIES OF DIABETIC AUTOMOBILE OPERATOR SAFETY

Author and Date of Study	Population	Major Findings	Comments
Paulrude (1981)	761 diabetic medically restricted drivers in Washington state	Average frequency of collisions per mile for diabetics was 28% higher than that for controls matched for age, sex, and estimated number miles driven. This difference was not statistically significant.	
Waller (1985)	2,672 drivers with known chronic medical conditions whose records were under review by the California Department of Motor Vehicles. 218 of these drivers were diabetic.	Accident rate for diabetic drivers was 15.5 accidents per 1,000,000 miles driven. The expected rate (based on the ages of the drivers) was 8.7. This difference is statistically significant.	Waller examined only those records that were under review. In most cases, these records were under review because of the receipt of a periodic medical report. This means that the majority of the sample of the diabetic population was made up of the diabetics whose disease was severe enough to warrant a medical exam every three or four months. Also, 52% of the diabetics in the sample had reported the disease voluntarily. 41% had a medically restricted license only after an accident or violation (35%), or a report made by a concerned law enforcement official (6%).
Crancer and McMurray (1968)	Driving records (from 1/61 to 10/67) of all medically restricted drivers in Washington State. 7,646 of these drivers were diabetic.	Diabetics had significantly (14%) higher average accident rates than age-matched non-diabetics. This difference was most pronounced in the 18-30 year old age groups.	Diabetic population consisted mainly of those who had declared their diabetes to the Department of Motor Vehicles. This is a relatively small proportion of diabetics accounting for less than 10% of the diabetics in the state. Also, the driving records for diabetics were compared to those for all Washington drivers. Thus, the fact that diabetic drivers tend to drive fewer miles per year than non-diabetics was not taken into account.

TABLE III.1

STUDIES OF DIABETIC AUTOMOBILE OPERATOR SAFETY (cont.)

Author and Date of Study	Population	Major Findings	Comments
Haunz and Brousseau (1984)	85 young diabetic drivers from North Dakota	33% of the subjects reported having at least one hypoglycemic reaction per week. 5% reported having reactions while driving.	
Ysander (1966)	243 diabetics (90 of whom took insulin) in Sweden.	Only 3.9% of these diabetics were involved in an accident, while 7.7% of the controls (matched for age, sex, license holding period, and exposure to traffic) were involved in accidents.	In Sweden, a physical examination is mandatory for a driver's license. Furthermore, physicians are encouraged to notify authorities of occurrences of diabetes. Diabetics are required to regularly submit medical certificates insuring close medical supervision.
Herner and Ysander (1962)	120 medically restricted drivers, 63 of whom were insulin dependent diabetics in Sweden.	Medically restricted drivers had no more traffic accidents than controls matched for age, sex, license holding period and distance driven.	
Frier et al. (1980)	250 insulin dependent diabetics attending the outpatient department of Edinburgh Royal Infirmary.	34.4% of these diabetics reported having severe or frequent hypoglycemia in the last 6 months. 34 patients (13.6%) were involved in an accident since beginning insulin treatment. 13 of them said hypoglycemia had been an important causal factor. Thus, while only 5.2% of the diabetics had been in an accident due to hypoglycemia, hypoglycemia accounted for 38% of the accidents these diabetics had.	Accident rates for non-diabetics were not reported.
Herner et al. (1966)	44,255 accident reports from 1954-1963 in Sweden.	41 (.1%) of these accidents were caused by sudden illness, only 3 were due to diabetic hypoglycemia.	

TABLE III.1

STUDIES OF DIABETIC AUTOMOBILE OPERATOR SAFETY (cont.)

Author and Date of Study	Population	Major Findings	Comments
DeKlerk et al. (1966)	8,623 diabetic patients admitted to hospitals in Western Australia during 1971-1979.	Diabetic male drivers age 15-54 had 2.8 times more hospital admissions as the result of traffic accidents than expected (based on age). Diabetic men over 54 and diabetic women did not have significantly more of these admissions than expected.	The authors acknowledge several possible confounds, for example, diabetics may be more likely than non-diabetics to be admitted after a car accident, even though their injuries are similar. Second, the diabetic population selected from hospital records may have been more sick or have more problems with their diabetics than other diabetics. Third, the amount of circumstances (e.g., city versus country) of driving were not taken into account.
Lashe (1985)	Not specified.	Approximately 10% of the accidents due to medical conditions other than alcoholism implicate uncontrolled diabetes with hypoglycemia as the causal factor.	Those with "uncontrolled diabetes" would probably not be eligible for pilot certification.

IV. REVIEW OF ARGUMENTS CONCERNING CHANGES TO THE REGULATIONS

Several organizations have either formally or informally expressed opinions as to whether the medical pilot certification criteria with regard to insulin-taking diabetics should be modified. In general, groups representing private pilots and diabetics are in favor of: (1) allowing qualified pilots to fly with a minimum of restrictions; and (2) permitting diabetics to engage in any activity for which they are individually qualified. On the other hand, much of the established medical community has reservations about allowing insulin-taking diabetics to become private pilots. The following table summarizes the positions of the various interest groups contacted during the course of this study.

Group	Description of Policy/Position
ADA	New policy statement - Diabetics should not be prohibited from occupations or endeavors for which they are individually qualified. Airplane pilots are specifically included.
AMA	No official policy - A high level panel of diabetologists has recently recommended that regulations pertaining to certification of oral hypoglycemia agent taking diabetics be liberalized, but that no changes be made in certification criteria for insulin-taking diabetics.
AOPA	Strongly in favor of modifying the current disqualification for insulin and oral hypolglycemia taking diabetics. Changes in blood glucose monitoring and other means of maintaining good diabetic control significantly reduce the uncertainly surrounding certification of diabetics under good control.
ALPA	Opposed to changing regulations disqualifying insulin-taking diabetics from becoming aircraft pilots; they are also skeptical about relaxing rules governing oral hypoglycemia agent taking diabetics. Airlines will not change their employment polices even if federal regulations are changed. Airline pilots' schedules are too unstable to be consistent with assured high levels of diabetic control. Potential loss of effectiveness of one pilot in a commercial airline cockpit due to medical incapacitation is considered to be a risk not worth taking with regard to drug taking diabetic pilots.
SSA	No official or unofficial policy. Glider pilots must sign a statement saying that they know of no physical deficiencies which would prevent them from piloting a glider aircraft. Responsibility for the veracity of this statement is the individuals own responsibility, as no medical exam is required.
ICAO	No drug taking diabetic shall be certified for a commercial or air transport pilot license. Oral hypolglycemic drug taking diabetics may be certified for private, glider and balloon pilot licenses if the drugs

diabetics treated by diet alone may be given if there is no evidence of ketoacidosis, signs or symptoms of hyperglycemia or hypoglycemia, and fasting blood sugar and 2-hour postprandial blood sugar is no greater than 140 mg/dl.

A review of the major arguments for and against certification of insulin-taking diabetic pilots is presented below.

Argument No. 1:

The prohibition for insulin-taking diabetic pilots was instituted when there was considerable uncertainty about the ability of diabetics to maintain adequate control of blood glucose concentrations. Recent technological innovations, e.g, blood glucose testing equipment and the insulin infusion pump, have enabled conscientious diabetics to better maintain near normal blood glucose levels. Since this equipment allows the incidence of hyper- and hypoglycemic episodes to be greatly reduced, the safety risks to insulin-taking diabetic pilots should not be so high as to require a blanket disqualification from piloting.

Response:

While it is true that there has been a dramatic improvement in technology for blood glucose monitoring and control, it is still not possible for diabetics to keep blood glucose levels perfectly controlled at all times. In fact, those diabetics who attempt to achieve near perfect control have more (usually mild) hypoglycemic reactions than those who are not as concerned about control (Goldgewicht, 1983). This is because the range of glycemic swings is not significantly reduced for those attempting strict control (Service, 1970), and therefore, lowered average of blood glucose levels tend to lead to an increased number of hypoglycemic reactions. Furthermore, those using the open-loop insulin pumps may experience more frequent hypoglycemic episodes than those using conventional treatment (Arias, 1985). Until more knowledge is gained about setting pump parameters (insulin infusion levels and times), the open-loop insulin pump can not be relied on to produce normal glycemic control in diabetics.

In addition, satisfactory levels of glycemic control demonstrated at the time of a medical exam does not guarantee that the diabetic will continue to rigorously control his disease. At a minimum, this argues for much more frequent medical reviews of diabetic pilots than is customary for other private pilots.

Argument No. 2:

Diabetics have proven to be capable automobile drivers with recent evidence (Paulsrude, 1981) of no significant difference in the rate of accidents between diabetic and non-diabetic drivers. If diabetics are proficient automobile drivers, why should they not be safe private pilots?

Response:

While some studies suggest no significant differences between diabetic and non-diabetic drivers, other studies (e.g., Crancer and McMurray, 1968, and Waller, 1965) show that diabetic drivers have significantly more accidents than do their cohorts. It is difficult to apply the results of these driving studies to hypotheses about flying proficiency for several reasons. First, the tasks of driving and flying are very different; flying is much more demanding and complex than driving. Second, the auto studies were based on diabetics with medically restricted licenses. This limited sample constitutes only a small percentage of all diabetics with driver's licenses; it includes only a small percentage of insulin-taking diabetics; and on average, those studied were older and more infirm than prospective diabetic pilots.

Based on auto research done to date, it is not reasonable make inferences about the relative safety of pilots (from auto accident rates).

Argument No. 3:

Insulin-taking diabetic pilots, no matter how conscientious, pose additional safety risks to themselves and others and, therefore, should not be certified as airplane pilots.

Response:

This argument is strongest for the commercial airline industry where the safety of many passengers is at stake. Even there, medical incapacitation has been shown to be the cause of accidents in an extremely low percentage of cases (Chapman, 1984). For student or private pilots, safety risks are generally confined to the pilot and perhaps a few passengers. Any increased safety risks associated with allowing insulin-taking diabetics to be certified should be considered in relation to those risks already accepted by general aviation pilots.

Argument No. 4:

The possible interaction of hypoxia and/or stress and hypoglycemia have not been adequately researched. Until they are, no change in the medical certification criteria for insulin-taking diabetics should be made.

Response:

Hypoxia is a dangerous condition which may effect pilots flying at altitudes above 10,000 feet if they do not have pressurization or oxygen equipment. However, unless there is a reason to believe that hypoxia will cause hypoglycemia to occur more frequently or that the combination of hypoxia and hypoglycemia will result in significantly more severe symptoms, it is unlikely that the interaction of hypoxia and hypoglycemia will cause the results of this study to change significantly (as there is only a small probability that both conditions will occur simultaneously and result in an accident). Stress has been shown to be generally associated with an increase in blood glucose and ketone concentrations (Hinkley, 1950). Since hypoglycemia (low blood glucose concentrations) is the largest safety risk for diabetic pilots, the stressful environment of flight should not significantly increase the risk of diabetic medical incapacitation.

Argument No. 5:

Because current regulations deny certification to drug using diabetics, some pilots who take oral agents or insulin might not fully report their status during periodic medical exams. In addition, some pilots controlled by diet alone might decline to make changes in their medical program (e.g., begin to use oral agents or insulin) even if it would improve their diabetic control. Both of these situations would tend to increase safety risks for currently certified diabetic pilots.

<u>Response:</u>

There is no information to confirm that either of these situtations occurs with any regularity. The impact of these possibilities on air safety is probably small, although this cannot be known with confidence.

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