**Brittle Diabetes Foundation Inc.**

 The Case for the Reclassification of

Brittle Type 1 Diabetes (BT1D) as a Rare Disease

and as a Separate and Distinct form of Type 1.

SUPPLEMENT 1. ***Classification of BT1D Based on***

 ***HbA1c Analysis***

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**Classification of BT1D Using HbA1c (A1C) Analysis. Supplement 1.**

 The ADA and medical practitioners place a great deal of stock on the efficacy of A1C as applied to cut points established for the different forms of, or degrees of, diabetes.

ADA Medical Care guidelines 2016:

A. 4.0 to 5.6 serve to distinguish normoglycemia – non diabetes

B. 5.7 to 6.4 distinguishes those considered to be pre-diabetes

C. 6.5 defines diabetes in general with Type

 1 differentiated from Type 2 by diagnostic testing

D. ≥6.5 with clinical extension to < 7.0 - Represent a

 Clinician’s target for achieving BG stability or control.

E. >7.0 reflects T1D instability, with degrees of glycemic

 variability, that serve to distinguish two distinctive groups

 of individuals.

1. Patients, who, with proper application of insulin therapy, can be stabilized or controlled the majority of time and lead relatively normal lives, reflects a “stable T1D” state.
2. There exists a unique form of T1D that is separate and distinct from “stable T1D” and is extremely rare, viz., Brittle Type 1 Diabetes (BT1D). The brittle form is characterized by key features that make it unique:
3. It defies conventional therapy
4. Its symptoms and maintenance leads to a disruption in daily life activities.
5. It is unstable, uncontrollable and unpredictable;
6. It is rare. Three numbers are generally found in medical literature to reflect the estimated number of BT1D patients:

3/1000 T1D’s, <1%, and one Brazilian study cites 1/50 T1D’s or 2%. Numerically this translates, using CDC data (1.5 million T1D’s), into 4,500 to 30,000 for the occurrence of BT1D.

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If we employ JDRF’s suggested number of 3 million T1D’s the range for BT1D doubles (9,000 to 60,000) in a USA population of 318 million people, still making it extremely rare.

 However, missing from this terminology description is a cut point that distinguishes the unstable but controllable (stable T1D) from those that fit the description of brittle. We also lack defining diagnostic criteria to distinguish between these two distinct and separate forms of T1D. This will not occur until the basic researcher separates those presently diagnosed as brittle from those considered to be stable in clinical trials that combine the two different diseases.

 Not until a clinical trial occurs that compares (an arbitrary number) 30 stable T1D’s to 30 BT1D’s in terms of diagnostic criteria such as auto-antibodies, c-peptide, HbA1c, glycemic variability in rate of occurrence and time duration, genetic anomalies, et.al., will we be able to set an HbA1c cut point or biomarker that suggests the likelihood of Brittle Diabetes.

A line graph description:

4.0-5.6/ 5.7 to 6.4/ 6.5 / 6.5-7.0/ 7.1 – unknown cut/ BT1D

(A) (B) (C) (D) (E) (F)

BDF offers ADA’s PPC this supplement to clarify its’ descriptive terminology position using solely A1C analyses.

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