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This declaration of Khabir Southwick DBA Natural Healing Consultants is based on his understanding of the precedent set by the successful “challenge before the U.S. Court of Appeals for the District of Columbia Circuit in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), ruled that the agency” (the FDA) “must permit health claims that do not satisfy the ‘significant scientific agreement’ standard as long as the claim can be rendered non-misleading by requiring a disclaimer. The Court examined possible disclaimers in some detail, and suggested that the FDA concerns regarding misleading information could, under many circumstances, be addressed by a disclaimer as simple as: ‘The evidence in support of this claim is inconclusive.’ The court also ruled that the FDA’s unwillingness to define ‘significant scientific agreement’ was a violation of the Administrative Procedures Act, in that the agency did not provide a clear standard that notified manufacturers of the FDA’s requirements, nor did it create a sufficiently clear standard upon which the FDA’s determinations could be reviewed. Comments on the proposed rule argued in light of *Pearson* that the FDA may not issue a final rule that prohibits disease claims but rather must choose the less restrictive alternative of permitting such claims, provided that they are accompanied with disclaimers.”[i]

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[i] The FDA’s definition of disease, for purposes of 21 U.S.C. 343r(6). From Sec. 101.93 certain kinds of statements for dietary supplements of the DSHEA: Dietary Supplement Health and Education Act. See Dumoff, Alan, J.D., M.S.W., “Defining ‘Disease’: The Struggle for Turf in Dietary-Supplement Regulation,” *Alternative and Complementary Therapies*, April 2000 issue, p. 101.

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In case of medical emergency contact your doctor and/or call 911 immediately.

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