


“The leaves of the tree were for the healing of the nations.”  
 (Revelation 22:2)

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# Diabetes and Markets for Diabetes Care: Double Blind Tests and Other Controversies

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**‘Diabetes and Markets for Diabetes Care’: A Criticism from an Empirical Viewpoint.**

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#### 1.Introduction

##### 1-1.Definitions of Diseases Evolve.

According to Oxford English Dictionary, a 'disease' is defined as 'an unhealthy condition of the body or the mind', or 'illness' and 'sickness'. 'Medicine' is defined as 'the science or practice of the diagnosis, treatment, and prevention of disease'. In most cases, diseases precede medicine. In other words, people suffer 'symptoms' first, and then, only after then, exert efforts for diagnosis, treatment, and prevention of such symptoms. Occasionally, this sequence is reversed. For example, during the 19th century, through breakthroughs in microscopes, the whole concepts of 'infectious' diseases started. For those diseases, the focus of the definitions themselves shifted from 'certain symptoms' to 'a certain germs observable through microscopes'. Before the advent of microscopes, 'malaria' was defined as 'attacks of high fever, shaking chills, and, sweating'. In contrast, the new definition of 'malaria' became "An infectious disease caused by obligate intracellular protozoa of the genus plasmodium". Many cases previously diagnosed as 'malaria' would not be diagnosed as such anymore, and, vice versa. So, as far as these newly defined diseases are concerned, we can say that 'medical technology preceded diseases'. Let's take another example. Up until a recent couple of centuries ago, 'fever' had also been thought of as a distinct disease. Now, fever is thought of as a symptom of diseases, rather than as of a distinct disease. Obviously, diseases are constantly being redefined to fit the social, economic and technological conditions.[i]

##### 1-2. Diabetes Cannot Be Misdiagnosed.

Likewise, Diabetes has also been being redefined. At first, 'diabetes mellitus' was literally 'a disease of sweet urine'. Then, there were 'thirst diseases', 'hunger diseases' and, interestingly 'ant gathering diseases' (as some sharp ancient Chinese observers noticed ants gather around sweet urine!). Now, diabetes is defined as a condition in which certain blood glucose levels are observed higher than certain numerical values. Obviously, here again, the definition evolved in response to the technological advances. An advent of diagnostic technology changed the definition of the disease itself. It is little wonder that there is no misdiagnosis in the case of diabetes. As diabetes itself is defined according to a certain reading of certain machines, there cannot be misdiagnosis of diabetes. It is not because the researchers did a great job, but, because the disease is defined around a certain diagnostic techniques. It is just a circular argument. Similarly, the definitions of 'High Cholesterol' and 'Hypertension' are also based on certain diagnostic techniques. Thus, there can not be misdiagnosis for those diseases, either. Not because researchers have accumulated knowledge after knowledge, but, because it is logically impossible to misdiagnose those diseases whose definitions are defined according to the reading of certain diagnostic measurements.

##### 1-3. A Name Tells Many Things

In relation to the evolutions of definitions of diseases, it is worthwhile to mention the emergence of such concepts as 'complications'. Those symptoms which had been formerly regarded as distinctive diseases were regrouped as 'complications' of certain other symptoms. This is purely a matter of convenience of analysis and treatment. Also, how a balance of power plays out among practitioners tend to determine this. Surgery was a part of a barber's job. The power relation during the last century resulted in what we have now. (Still, the barbershop carries the sign of bandage and blood. If the trend of more and more cosmetic surgeries may eventually lead to a regulation that all the cosmetic surgeries should be handled by what we call 'beauty salons'.

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The definitions of diseases also tell us about how advanced our knowledge about those diseases is.[ii] If a disease is defined specifically and narrowly around a set of definite causes, it is likely that we have relatively a good control of the disease. Its prevention would be about minimizing the exposure to those causes, and, its treatment would be the removal of those causes. It is quite likely that we have somewhat better functional control of such diseases. On the contrary, when a disease is defined not around definite causes, and, the definition itself is not narrowly specialized, it is likely that our understanding of such a disease is still very shallow and naturally our functional control over it is also very poor. For example, such diseases as Type II diabetes, hypertension, and high cholesterol, the definitions are around the reading of diagnostic measurement of certain aggregate 'indices', not around definite functional causes. In general, our functional control over these 'index' diseases is relatively poorer than our control over infectious diseases. Like those macroeconomic 'indices' such as unemployment rates and inflation rates, these aggregate indices such as blood glucose levels and blood pressures are determined by infinitely many factors. Obviously, the complexity and difficulties of solving the inflation problem of a large economy are on a different dimension from the complexity and difficulties of solving a murder case. Analogy is straightforward. Treating diseases like Type II diabetes is a whole lot more complex than treating malaria.

## **2. Inherent Complexity and Methodological Difficulties in Type II Diabetes researches.**

### **2-1. We Have Infinitely Complex Bodies.**

Human bodies are typically 'infinitely complex' systems. 'An infinitely complex system' is a concept coined by mathematicians.[iii] The more we analyze the causes of a symptom in an infinitely complex system, the more things to be analyzed emerge to the effect that we will never reach the point where there are no further factors left to be analyzed. There will always be more, infinitely more factors and data to be analyzed no matter how much we collect and study. Weather is an example of this 'infinitely complex' system. Human metabolisms are classic examples of infinitely complex systems. For these systems, there is no way of collecting all the data, and thus, a complete analysis is inherently and logically impossible. Thus in these systems, perfect forecasts are always impossible even over a short period of time. Also long term forecasts always have very poor accuracy. For these systems, there are always infinitely too many factors to consider. Infinite numbers of simultaneous interactions are taking place constantly among infinitely many components. These characters of these interactions are ever evolving. There are always an infinite number of determinants for an aggregate index defined with respect to a particular moment of time. For example, there are an infinite number of determinants that determine the inflation rate of the United States for the month of May 2001. Likewise also an infinite number of factors determine a person's blood glucose levels and blood pressure levels at certain moments. Furthermore, these aggregate indices, they themselves are determinants of other infinitely many other factors in the systems. As Inflation is a cause of infinitely many other social and economic problems, so a high blood glucose level is a cause of infinitely many health problems.

### **2-2. Dismal Science vs. Witchcraft**

Type II diabetes is a disease whose definition is based on the blood glucose level. As blood glucose levels are aggregate indices of infinitely complex systems, our bodies, there are always infinitely many factors that determine the blood glucose levels. In other words, the definition of the disease which we call Type II diabetes, defy complete understanding/ control of the disease. No matter how much research we do, there will never be a day when we can declare that we fully understand Type II diabetes. Therefore, there will never be a day when we find a cure for Type II diabetes based on full understanding of the disease, even though we may have a luck of successful control of the disease without fully understanding the disease. We often hear that by 2030, after 20 billion dollars of research efforts, we will finally conquer Type II diabetes. Such statements are nothing more than a

cheap witchcraft. As long as we define the disease by certain reading of aggregate indices (blood glucose levels), there will never be such a time. No matter how much science advances, a perfect short-term control of blood glucose levels is impossible, while reliable long-term control of blood glucose levels is also very unlikely, not to mention perfect long-term control. Of course, in every six months, we read in the news that a scientist found a 'candidate' gene for Type II diabetes. But, this scientist always hastens to hedge himself by saying "But, there should be a lot more researches to be done in this area and it is a few years down the road before this discovery actually helps the patients". Diseases like Type II diabetes and hypertension are bound to be determined by infinitely many factors. The chances of discovering genes for 'boneheadedness' are a lot better than that of finding Type II diabetes genes. No doubt, many scholars will get their work published by disclosing these candidate genes, and may receive quite a bit of research funds. Who knows? Gullible venture capitalists may put up enormous sums of money, expecting to find even more 'gullible' investors in the stock markets. It is obvious from the start that there can no such genes, by definition of the disease. Even to the eyes of an outsider, it is obvious that Type II diabetes is a protein level expression governed by infinitely many environmental factors, not a gene-level expression. To claim to have found such genes, is foolish, at its best. It can only be labeled as 'dishonesty', even 'fraud', even 'witchcraft'. Due to its incompetence and failure of good predictions and good treatment, economics is often called a 'dismal science'. Many studies of Type II diabetes are candidates worthier for such a title. This author argues that "there should not be a lot more studies done in such an area and even after many years, the patients will surely not benefit from such discoveries."

Another trait of such diseases is that once they start, they tend to aggravate over time. This author argues that this trait also follows directly from the definition. Any 'stable' complex system has self regulating functions. Therefore, something going wrong in those key aggregate indices of such a system is synonymous with something going wrong with its self regulating functions. Of course, when something goes wrong with the self-regulating functions, the system will cease to regulate itself, and those aggregate indices will aggravate. This tautology again comes from the way we defined such diseases and such systems. It is just a circular logic among definitions: when we say 'once Type II diabetes starts, it worsens on and on', it is simply a play of words. We just defined the disease like that. No new information is added there. By the way, on the average, Type II diabetes, when unattended, is known to progress by 100 mg/dl rise in the blood glucose levels every ten years.

### **2-3. Failure of Conventional Statistics in Researches of Type II Diabetes**

For these diseases, it is highly likely that simple conventional statistical approaches tend to lead to serious errors we call 'Identification Error in Simultaneous Equation Systems'. Here, we need a little bit of explanation.[iv] The error happens when A is regarded, in a statistical model, as determined by B, but in fact A and B are mutually affecting each other. In statistical terms, we say that B is erroneously (or spuriously) modeled as 'exogenous' while being 'endogenous'. If we make this error, we will draw wrong conclusions about the cause and effect. Sometimes, we erroneously draw an opposite conclusion to the true causal relation. An easy example: a city tries to find the causes of the increase of the crime rates. In trying the statistical model, they use many variables as explanatory variables to see which gives best statistical 'fit'. Imagine that the number of policemen shows stable statistical correlation with the crime rate. At that time, if one concludes that policemen cause the crimes, it is a wrong conclusion. More policemen are hired in response to high crime rates. Not vice versa. The number of policemen is not an exogenous variable, but an endogenous variable. By using erroneously an endogenous variable in an equation as exogenous variable, one may establish very wrong conclusions about the causes and their effects. The example of policemen and crime rate is so obvious that people seldom make such mistakes. But, in the medical science, the mistakes take a lot more subtle forms so that a lot more people make such mistakes, even those people with Ph.D's.

For example, a researcher claims that he found that a substance called X-789 that lowers the blood glucose level by 5% on the average in ten of test subjects. (Of course, most researchers who are worthy of their salts never forget to add that "the conclusions are temporary, we need more research", which, they think, would exonerate themselves from all sins including 'boneheadedness') Also, he invariably performs so-called Randomized Controlled Double Blind Test (RCT hereinafter). Usually, such RCT's are successful. (Have you ever seen a research that does not pass an RCT?) Does this warrant a conclusion that X-789 is helpful in lowering blood glucose levels? Not necessarily. We can not make such conclusions no matter how temporary they may be. In order to draw such conclusions, we should be able to statistically control all other factors that influence the blood glucose levels, except X-789. In other words, we should know at least the statistical correlation between all those variables and this X-789. Without this knowledge, any conclusion is subject to the potential of serious errors. Who knows? X-789 is so expensive that when people buy it, they can not afford good meals, so that their blood glucose levels become lower. Also, the only place people can buy X-789 could be very high up in the mountains so that people have to climb very hard to purchase X-789. What else? X-789 could, in fact, primarily raise the blood glucose levels, and our body's defensive mechanism is triggered to lower the blood glucose levels as a response. As a result, we may be able to observe somewhat lower blood glucose levels temporarily, while those defensive mechanisms are irreparably damaged due to the overwork. The particular defensive mechanism may be triggered only so many times in a person's life, after which resistance develops. In addition, like fingerprints and DNA sequences, every human being is different. Even identical twins are infinitely different from each other due to the exposure of infinitely different environments. Adding one human sample just adds more idiosyncratic individuality. It is a typical symptom of infinitely complex systems. If we recognize that there are 10 different attributes between samples, then, unless we add more than 10 samples, the statistical power of inference actually diminishes when more samples are added. If we recognize that there are 1000 different attributes, addition must be more than 1000. Otherwise, adding more samples in fact weakens the power of statistical inference. What if there are an infinite number of attributes? Conventional statistics fail right there. They are bound to fail no matter whether the conclusions are temporary or not, no matter whether an RCT is performed or not. Much research is done this way. Their conclusions are not only temporary but also unwarranted. Very unwarranted. Saying "this is a temporary conclusion, and we need more studies" should not be allowed to be used as an excuse for saying something wrong that are just wrong.

#### **2-4. Double Blind Tests Are Often Done Blindly**

In any way, Randomized Controlled Double Blind Tests (RCT's) are widely misused. The original purposes of RCT's are not paid attention to any more. Invariably, whenever a new substance or a new treatment is proposed, people almost invariably ask whether an RCT is performed in the test. Frankly, this author believes that 99% of those people who ask such a question do not know what an RCT really is (of course, this is a temporary conclusion, and there should be more studies...) In most cases, people seem to just feel that the act of asking such a question would make the questioner look more scientific, or, would somehow prove that the questioner knows what an RCT is. In fact, asking such a question when such a question is not warranted not only proves that the questioner is unscientific but also that the questioner does not exactly know what an RCT is. The concept of RCT's are originally developed in Islam World in the Middle Age by Abu Ali Iben Shina (980-1037 AD). It became famous after being used to prove the efficacy of Vitamin C. After World War II, RCT's became popular among major American pharmaceutical companies who originally used the tests under particular and highly specialized circumstances. An RCT is a very good tool to see what difference 'patient's knowing the content of a drug' would make in the efficacy of the drug because it is made for such a purpose. It is a very poor tool for any other purposes than the measurement of the psychological effects of the test subjects knowing the purpose of certain treatments. Moreover, an RCT can be an effective statistical

tool when a candidate explanatory variable is known to be 'orthogonal' in relation to all other explanatory variables. In other words, an RCT is helpful when there is an identified active ingredient and the efficacy of the active ingredient is known to have no correlation with all other factors that affect the target diseases. When there is no identifiable active ingredient, or, when there are many active ingredients, or when the ingredients are not necessarily 'independent' from all other facts that affect the diseases, an RCT is not a helpful statistical tool. Sometimes, it even delivers the opposite conclusions. We can confidently predict that RCT's used for purposes other than their intended purposes and under wrong statistical premises are bound to fail. Such a prediction is even temporary, and does not even really require further studies.

We often hear that RCT's are used to compare the effect of a treatment with respect to a placebo effect. In order for an RCT to attain that purpose, it should be possible to construct a 'good' placebo. In other words, a researcher should be able to construct a material that looks, tastes, smells the same, but, has no relationship with any part of the mechanisms of the diseases and has no unknown relationship with all and each active ingredients that are tested. It is not easy to construct a 'good' placebo. Furthermore, it is logically impossible to construct a placebo when active ingredients are not known. In other words, so-called RCT's performed on products that contain unidentifiably many active ingredients are based on no or little, if any, scientific bases. For example, can we use an RCT to see the effects of a herbal combination on Type II diabetes? Absolutely not. At first, one should be able to construct a placebo to the herbal combination. When we do not know exactly what the active ingredients of the tested herbal combinations are, how can we construct the placebo? And when we could not construct the placebo, how could we do a double blind test? Also, why do we need an RCT to start with? We are not interested in the psychological effect, per se, of a person's knowing that he is taking a herbal combination. We are interested in whether the herbal combination is helpful or not. We do not really care whether the help is from psychological, or religious, or, socio-political reasons. And even if we care, there is no way of telling it. The danger is that RCT's are often demanded when it is impossible to do them, and a bigger danger is that some are actually doing them. The most dangerous situation is that people who refuse to do so are regarded as being unscientific.

Also, in so many researches based on RCT's, the researchers are confused between a Null Hypothesis and an Alternative Hypothesis. In other words, their focus is seeing whether the placebo is as good as the drug, while the purpose of the research should be seeing whether the drug is helpful or not. Here we need a little bit of explanation. Unless trained in statistics, we may find it difficult to distinguish the difference between the following two statements 1) "The probability of a person gets bitten by a dog in 2003 is 90 percent" and 2) The probability of our being wrong in rejecting the null hypothesis that a person is not going to be bitten by a dog in 2003 in favor of an alternative hypothesis that a person is going to be bitten by a dog in 2003 is less than 10%" Mind-boggling? Let's just say that they are very different in actuality many researchers exploit those who are confused about it, most often by misusing the statistical tools, especially those concerning RCT's. Frankly and sadly, this author believes that in the area of Type II diabetes, research that uses the RCT's correctly is not the norm, but a very scarce rarity. In fact, the concern of this author is shared by many prominent scholars such as Ted Kaptchuk.[v]

### **3. Confusions and Errors in the Treatment of Type II diabetes.**

#### **3-1. Imperfect Markets.**

In the above, serious logical difficulties that flow directly from the way we define Type II diabetes were discussed. In this section, some structural problems observable in the diabetic care markets are to be discussed. Confusions, misunderstandings, and miscommunications, even misrepresentations characterize this market. Also, there are thick power politics in which the exploiting interplay the exploited. Correct criticisms and false accusations fly sometimes with sincerity but often as tactics.

The diabetes care market is not unlike all other 'imperfect' markets where the central issues are not clearly defined, and where a lot of money is involved, and where there are heavy regulations and laws that do not clearly know what and why to regulate. The law of economics says that "in an imperfect market, there are some exploiters and some exploited. In this section, those food chains and power politics among various players in this market are explained.

In almost every civilized country, the diabetes care market is practically the single largest medical care market. By some measures, the direct and indirect costs and expenses that incur for the diabetes care, thus, the total revenue for the diabetes care provider directly and indirectly is approximately close to the size of the all the rents paid to commercial real estates of a country. For the US, this sum is \$150 billion a year. We are involved with huge numbers here.

### **3-2. Fever Associations and Diabetes Associations**

Imagine that in a country, there is an association called "National Fever Association (NFA)" and all the people who became concerned about their fever should go to a doctor who is a member of the NFA. The NFA actually determines what a 'fever' is, and how to treat it. Anybody who does anything different from NFA rules is answerable to the government if he is unlucky. Of course, the NFA has no cure for the fever, and, having spent billions dollars on the research, always produce only temporary conclusions, and need to await further studies. Only few people question the wisdom of treating fever as a distinct disease, rather a symptom of other distinct disease. We could easily see the absurdity of such an imaginary situation. Truly, "an attempt to organizing a National Fever Association" would be funny because a fever can be caused by many reasons, and lead to many problems and we can gain a lot more by looking at 'fever' from viewpoint of other diseases whose the functional structure we understand better. Of course, if we are stuck with the habit of treating the fever as a distinct disease and try to find the cure, we will never be able to find it, only temporary controls. But, here we have Type II diabetes, a disease which is defined around an aggregate metabolism index, the blood glucose level, like the body temperature, thus, logically impossible to find a particular cure, and, almost impossible to do any scientific analysis based on conventional statistics. This author is of opinion that if an NFA were a funny organization, a Diabetes Association should be an equally ridiculous organization, (except for their invaluable contribution to the study of Type I diabetes). The definition of Type II diabetes is simply dysfunctional. It is just a circular restatement of the question itself, not providing any operationally helpful value. It is just little more than linguistic Anglo-Americanization (or just rephrasing) of the Greek phrase, Diabetes Mellitus. This author is of opinion that the whole body of Type II diabetes cases should be totally re-grouped and re-organized according to the functional differences.

Both pneumonia and malaria can cause fevers. And we are a lot better off by thinking of them as two different distinct diseases. Fevers were symptoms of those other diseases, and clues to the diagnosis of such other diseases. We are better off by not letting a National Fever Association tell us what to do or what not to do. Except for acute cases, the control of fever itself is not the goal of the treatment. It is an index to be observed. Likewise, insulin sensitivity deficiency is a totally different malfunction from insulin secretion deficiency, even though both may lead to higher blood glucose levels. We are much better off by treating them as two distinct diseases. The blood glucose level should be treated as an index to observe, not the treatment goal itself.

### **3-3. Familiar But Absurd Conventional Treatments**

Even though a certain treatment may lower the body temperature, we seldom appreciate the treatment very highly unless the treatment attacks the causes of fever. This is not what is happening in the treatments for Type II diabetes. Various distinct different causes that lead to high blood sugar are treated indiscriminately as the same, and combinations of highly controversial treatments are

administered indiscriminately because they lower blood glucose levels temporarily. It is like continuing to administer a combination of Tylenol and Aspirin no matter what the causes of the fevers are. If the fever does not disappear or aggravate, simply more dosages would be given. If this still does not work, and even resistance develops? Well, that's just life. Does this sound absurd? But, doesn't it sound familiar too?

We are doing exactly the same, 'absurd' thing when it comes to treating Type II diabetes: A) All Sulfonylureas drugs (under many different brand names) are basically squeezing more insulin from pancreas. What if the pancreas is already too tired? What if high blood glucose is from low insulin sensitivity, and not from lack of insulin? What about the damage inflicted on the liver and kidneys? B) All Biguanides drugs are basically blocking the intestines and livers from absorbing glucose. And all Alpha-Glucosidase Inhibitors block the working of digestive enzymes. In other words, they are all producing artificial indigestion. This is the practice of dangerously simplistic logic. (You see blood that high blood glucose levels is a disease. So, you want to remove blood glucose. Glucose comes from starch eaten. Ok. Either reduce the starch eaten or make it sure that the starch eaten does not get digested and absorbed.) Thank God that they are not making drugs for headaches according to the same logic. (Headache is a symptom in the head. So remove it?) Like any witchcraft, illogical studies in Type II diabetes come with big technical terminology. Instead of saying "you ate a big meal, so your blood sugar goes up", they say "post-prandial BGL increase after carbohydrate intake". C) Some insulin sensitizers are simply increasing the glucose storage capacity of the liver. Well, what if the capacity is already overburdened? No wonder those drugs caused not so few sudden liver deaths, and were taken off the markets. Of course, taking them off the markets happened only after tens of billion dollars increase of stock prices. (Let's not go into the details of the disclosure failure problem of the insider information toward both the drug and financial markets). The above A), B), C) are virtually the exhaustive list of the pharmaceutical drugs we have for Type II diabetes. All are based on fairly overly simplistic logic and all have serious side effects even though RCT's after RCT's have been done on these drugs.[vi]

### 3-4. Logical Alternatives

This author favors a few (not all) alternative medicine approaches[vii] so far as Type II diabetes treatments are concerned. The logic is obvious. We already know that all these pharmaceutical drugs have serious problems, and we also know that some alternative approaches have no such problems. So, as long as we could control the blood glucose levels, the approaches that are known to have no problems are superior to the approaches that are known to have them. The alternative medicine approaches this author favors should have the following attributes: A) They should use some combination of 'foods' or 'exercise'. In other words, they should be mild, not invasive. B) The 'foods' and 'exercises' should be recognized as safe by both tradition of long history and scientific tests. C) The 'foods' and 'exercises' should make observable desired changes in the state of the Type II diabetes. D) The 'foods' and 'exercises' should be economically affordable.

As explained above, there are a few reasons why this author prefers these 'foods' and 'exercises' approaches to the conventional pharmaceutical drugs. A) at first, the pharmaceutical drugs are 'known' to have serious side effects while these 'foods' and 'exercises' are known to have no such serious side effects. One may still argue that the side effects of the pharmaceutical drugs are well studied and well predictable and even some 'foods' and 'exercises' sometimes have some side effects. But, as a general rule 'foods' and 'exercises' are known to have much lesser side effects than those of pharmaceutical drugs. Contamination and dangerous interactions problems are possible, but rarely observable in practice. This author has had five years of experience with quality control while handling tons of hundreds of herbs. However, there was only one case of lead contamination that was slightly over the legally acceptable standard.[viii] B) 'Foods' and 'exercises' can be relied upon for long



periods of time, while long-term uses of pharmaceutical drugs invariably lead to serious problems, such as development of resistance. 'Foods' and 'exercises' seldom, if any, have this problem.) 'Foods' and 'Exercises', if well used, are just as effective as pharmaceutical drugs, if not even more effective. In sum, the logic of this author's favoring 'food' and 'exercise' approach is quite a simple one. "In order to solve one problem (i.e. controlling or treating Type II diabetes), one solution (i.e. pharmaceutical drugs) has a known and serious problem, and the other (i.e. 'foods' and 'exercises') are known to have no such problems. Therefore, as long as the latter produces the same efficacy than the first, the choice is obvious". The choice becomes ever more obvious when the latter produces even better results. Later in this paper, we will investigate a few criticisms against the above argument and some replies are also given there. This author is of the opinion that with all those criticisms and weaknesses, the 'Foods' and 'Exercises' approaches are still a lot better choice than single handed exclusive reliance on 'pharmaceutical drugs'. Especially, when these 'Foods and Exercises' approaches are wisely combined with (supplementing) conventional pharmaceutical treatments, the superiority of these mild approaches becomes substantial. Often, the 'Food and Exercise' approaches produce unexpected good side effects, including improvement of general health. Also, often, the effects of these mild approaches last longer. According to the experience of this author, it is not rare to observe semi-permanent reversion of Type II diabetes that have already progressed fairly seriously. As a rule of thumb, this author is of the opinion that the conventional pharmaceutical drugs should be used when it is proven that non usage will lead to irreparable and serious damages to the health of a patient. As long as there is a mild alternative, it is better to use the alternative.

Some statistical intuitions may be helpful here too. In statistics, independent variables that have larger variance usually produces better statistical explanatory powers. In drawing a watercolor landscape, the brush and ink are better tools than a razor dipped in ink. Of course, a razor can be a better tool for certain purposes, like etching on a copper plate. But, in the case of painting a watercolor landscape, the brush is a better tool. Treating Type II diabetes is closer to painting watercolor, than to etching. Pharmaceutical drugs are excessively and unnecessarily invasive to our bodies.

#### **4. Academic Witchcraft and Collusion:**

##### **4-1. "Let us exclusively cheat you!"**

In the year 2000, this author had a chance to visit the largest bookstore in Seoul Korea, where an entire section was devoted to 'diabetes'. More than a hundred books about diabetes were being published and sold to the general public. With very few exceptions, those books starts with a stern warning, "There is no effective treatment for diabetes. Do not be cheated by anybody, especially, a health food sales person". But, in the later pages of the books, there would be sections on "How to treat diabetes effectively". Even the book written by a former president of the Korean Diabetes Association had the same structure: an opening that warned, "There is no effective treatment. Do not be cheated by anybody" that was followed by sections involving "treatments of diabetes". This author was completely confused. What on earth are they talking about? If there is no effective treatment, how can their books have 'effective treatment' sections? Even funnier, every so-called "leading experts in the field" appear on TV, and declare that "there is no effective treatment for diabetes, and do not be cheated by anybody" as their voices tremble with righteousness. Within 10 seconds, however, they infallibly begin to explain about "effective treatments". Basically to this author, their positions seemed to border on "Do not be cheated by anybody but me".

Recently, the 61st "so-called" scientific session of American Diabetes Association was held in Philadelphia in June 2001. Many valuable researches were presented. But, This author finds some of the research very troublesome. For example, the research that drew most attention was basically saying "If HbA1c can be maintained within a low range, the chance of developing diabetic

complications can be lowered". But, Isn't HbA1c just another way of defining diabetes among a few other measures? Not too much unlike the temperature measured in Fahrenheit being just another way of measuring the temperature in Celsius. To this author, the logic, even if there is any, of the conclusion of the research sounded so circular. The conclusion is nothing but "if you do not have diabetes, the chance of diabetic complications can be very low". What else did he expect? Did he expect that diabetes patients have lower chance of having diabetic complications? There is nothing new, nothing valuable, nothing amazing in such researches, except the fact that such researches are accepted and presented at the 'scientific sessions' in such a prominent organization. Imagine that a researcher gets a standing ovation after reporting a similar conclusion in 85th scientific session of National Fever Association meeting: "If one maintains the body temperature below a certain number in Fahrenheit, the chance of developing complications from high body temperatures (measured in Celsius) is smaller". When such studies like these are not ridiculed, but respected, we know that something has gone wrong.

#### **4-2. "Foods are allowed to be bad, but they are not allowed to be good."**

As this author's company produces food products that are known to be helpful in controlling blood glucose levels and often reverse the progress of diabetes itself.[ix] This author occasionally faces criticism by so-called diabetes experts: "Your product is a food. One can not say that a food can be good for diabetes. It is illegal" Frankly, and to put it nicely, this author believes that such an argument is foolish. If one can say that some foods are 'bad' for diabetes, everybody should be allowed to say that some foods are 'good' for diabetes, if they are 'really' good. There are tens of hundreds books that explain and recommend foods good for diabetes. Diabetes cookbooks, glycemic indices of tens of thousands of foods...are they all illegal? The question is "how good a food is for diabetes, how well one proves such a claim and how one should accept or reject such claims". There is no law that stipulates that any food cannot be good for diabetes. Even if there were such laws, it would still not change the fact that there are tens of thousands foods that are good for diabetes.[x] If there were such laws actually, one can easily guess who lobbied for such laws.

#### **4-3. Publication as Religion**

There are reasons why this absurdity continues. First, if a researcher writes a research paper in which he shows that a food is helpful in controlling diabetes, the chance of having that research published in peer-reviewed scientific journals is almost nil. On the contrary, if a researcher tests a substance recently developed by a European pharmaceutical company that kills 56% of the tested mice, and 73% at a higher dosage, the paper will be published at least at one of the journals as long as the author keeps on submitting it. Of course, nobody reads it, and nobody cares. But, the researcher gets one more line in his resume. In academia, it is the number of such lines a researcher has accumulated that is important, rather than what real differences these researches have made. Hiring, promotion, distribution of the research funds are all determined by how many lines a researcher has in his resume. The question "did it really help anybody?" is seldom asked because they all know that nobody is helped. Too many researches end with, "this is still a temporary conclusion and further studies are needed". If the conclusions are temporary, why do the researchers not keep them to themselves? Publication in these peer-reviewed journals almost became a religion among researchers. It has become a goal to be pursued at any cost. For these people, intellectual works that are not published, are all inherently contemptible, no matter how much 'real' help such works may bring to 'real' people.

As explained in the above, this author's company is producing a series of food products that are helpful for diabetes. Some previous versions of a few of our products were originally developed and tested by prominent scientists at renowned research facilities. But, these scientists are so concerned about their names being disclosed in relation to these products. Sometimes they even deny their

involvement. They seem to fear that their 'academic and scientific' reputations were going to be ruined if their names are revealed in connection with these 'foods', the research of which are not publishable in peer-reviewed 'academic and scientific' journals. In their minds, 'science' is something analytical and 'foods' are not scientific enough. This summarizes the circular logic of the opinions of many so-called diabetes experts. In their evaluation of 'foods good for diabetes', it does not matter what statistical proofs are presented, as they often have a very poor understanding of statistical tools. Invariably, they request a double-blind test, not knowing what the double-blind tests are testing, and, why they are testing them. As this author pointed out earlier, the statistical tools these researchers use in their own researches are so flawed that this author could not believe that they were serious in drawing any conclusions, even temporary ones. But, for them, those sub-standard statistical tools and faulty analysis are OK as long as they are published.

#### **4-4. Vested Interests in a Huge Market**

As pointed out earlier, over 150 billion dollars a year are spent in the US, directly and indirectly for the care of diabetes, and billions of dollars are spent in the research of diabetes all over the world. It is not difficult to imagine that there are already well established vested interests with huge resources. Pharmaceutical companies, associations, doctors, and researchers are all components of these established interests. It is also known that one quarter of all medical expenses are directly and indirectly related to diabetes. In order to join the club of established interests, one has to either spend hundreds of millions of dollars or years of highly competitive training. Any new manufacturers' entry to the 'products' market is strictly controlled by the Food and Drug Administration, while the entry to the 'service' market is strictly controlled by American Medical Associations. The established manufacturers and the M.D's in this market are two peaks of the food chains while ordinary patients and their families are at the bottom of the food chain. Some statistics show that in one year, the pharmaceutical companies spent approximately \$15,000 of promotional support per M.D, paying for golf trips, conferences in exotic resorts, and expensive gifts. Somebody has to pay for it, right? In order to defend this lucrative market, they use many methods: Requiring double-blind tests while no double blind tests are possible, silencing any claims unless hundreds of millions dollars are spent.[xi]

#### **4-5. Dire Consequences of Market Imperfection.**

This author still does not believe that there are ill-intentioned conspiracies. But, this author strongly believes that a huge amount of resources are misdirected due to the way we define this disease and the habitual way we think of the questions themselves. The consequences take the form of unnecessary sufferings and foregone opportunities.

If one tries to control over a long period of time macro metabolism indices (like the blood glucose levels) with single component chemical drugs, serious side effects will inevitably surface after a certain period of time. But, as long as this side effects are relatively well recorded and within a certain boundary, the FDA will give permission to market the product. Once such an approval is given, huge stock price jumps happen. But, for the reasons explained above, it is a matter of time that the deadly side effects begin to take the tolls. Unless an outrageous fatality happens immediately and widely, products are seldom taken off the markets. Fatal cases are seldom brought to the court since an ordinary patient generally has no means to prove their cases. Even if they are brought to the court, the cases are often settled out of court. Also, doctors are well protected for prescribing these drugs. Insurance companies also are willing to provide the coverage as this is purely a game of chance for them. Of course, side effects and dangers are clearly warned of in small letters. The problem is not that the side effects are not warned of, but that the chemical drugs are presented as the only options.

They all seem to know the danger of allowing other options entering the market. Once good products emerge, big pharmaceutical companies usually attempt two things: 1) Predatory acquisition: buying

up those new findings so that their monopoly can be maintained. (For instance, when our product was being introduced to the market for the first time, a large Swiss pharmaceutical company offered a buy-out for \$25 million dollars.) 2) Once they fail in predatory buyout, they start indiscriminate attacks on the products so that the products can not survive commercially. (For instance, typical attacks are "Your products are foods. It is illegal for you to say that it is good for diabetes", "Your Products are not Double Blind Tested", etc... Sound familiar?)

In the US, 100,000 people die a year directly of side effects of pharmaceutical drugs. The 4th most frequent cause of the death and hospitalization is the side effects of these pharmaceutical drugs. These statistics are only about those acute obvious cases in which serious sided effects of drugs are clearly proven to have appeared over a short period of time and abruptly, drawing attentions of people. If we count include those cases in which the side effects of drugs appear gradually over a long period of time in an accumulative way, and those cases in which the side effects lead to the death indirectly, the above number will multiply many times. Also, if we look at some chronic health problems and their causes, we have reasons to be very concerned. For example, this author believes that more than half of the kidney failures for diabetes patients are directly attributable to these chemical drugs than to diabetes itself.

That is why we have to pay some attention at least when some one claims that some 'foods' are good for diabetes. One should not discard it as 'unscientific' without looking at the evidences. The alternative to these foods are serious side effects which many people suffer from permanently and many even die of.

## **5.Serious Problems in the Non-Establishment.**

### **5-1. They come and they go**

In fact, there are many plants and herbs that are proven to be helpful for controlling blood glucose levels. All over the world, hypoglycemic effects of about 3,000 plants and herbs are thoroughly studied and well recorded. This author believes that there are a lot more that are helpful but not recorded. Therefore, it is simply an absurdity to say that no herbs and foods are good for diabetes. The question is, which one is how good for what?

Also, we can expect that some combinations of such many plants and herbs are often marketed as 'new' discoveries. In most cases, these 'new' discoveries do not last more than six months in the market due to tremendous market resistance, and technological difficulties to be explained below. Obviously, these new discoveries can not have many cases observed over a long period of times. They usually rely on a few cases of 'personal testimonies'. These products do not last long enough in the market place even to allow simple most rudimentary sampling. Even though there are possibilities that some of them are truly good products, there is no way of statistically establishing the efficacy due to excessively short product lives. Most of them just come and go. The following are some of the reasons for such short product life.

### **5-2. Difficulties in Establishing Intellectual Properties**

It is extremely difficult to protect the intellectual properties for these 'new' discoveries. Patenting is not very helpful at all because there is no way of prosecuting the violators even when other people infringe on the intellectual properties of these products and produce copycats. Once mixed and processed, there is no way of telling that one product is really a copycat of another product. Also, patenting itself is often not as straightforward as chemical drugs. This difficulty in establishing and protecting intellectual properties poses fundamental obstacles for investing serious resources in researches or marketing efforts. Manufacturers would not spend a lot of money unless they are sure that their spending money leads to their making money later.

In order to overcome these difficulties, manufacturers should try to establish loyalty to the brand names and/or efficient distribution networks. Good efficacy is not enough by itself for a non-establishment company to survive in the market. This author believes that any manufacturers in the non-establishment should realize this difficulty of intellectual property protection at an early stage. This author's company relied on obtaining a number of patents on peripheries, (not on the core) of the technologies we have. The core of the technologies is protected in the form of trade secrets. So, for us, the brand name establishment, peripheral patenting, sales networks and trade secrets, all combined are protections. Difficulties and costs of manufacturing processes and marketing difficulties seem to offer additional protections.

Furthermore, for almost all the natural products, it is impossible to single out the 'active ingredients' responsible for the efficacy. There are too many possible combinations of active ingredients and too many interactions among these candidates. Especially, the number of candidate active ingredients easily grows to millions when combinations of herbs are brewed together. Also, it is a well-known fact that any natural product has a shorter shelf life no matter whether it contains preservatives. Even with strong preservatives and no microbiological activities and in vacuum, various components of the natural product tend to interact and their chemical structures tend to change over time.

Thus, it is impossible to figure out modes of actions completely, even though it is possible to figure out intermediate levels of modes of actions. There is no way of getting an FDA 'drug' approval under the current legal environment. Thus, manufacturers of natural products cannot rely on the stock market as a source of funding. All of the needed investment fund should come from a few investors.

Also, due to this difficulty in identifying the active ingredients, these products face serious legal and financial limitations in advertising and marketing after the development. Insurance companies cannot easily provide the coverage for these products both for the patients and the practitioners. In often cases, financial risks are simply too big for serious money to be invested in developing, manufacturing and marketing of natural products for diabetes.

Moreover, there is no perfect method standardizing these natural products. Even genetic cloning and hydroponic farming would not remove all the idiosyncrasy of natural products. The closest one can get is 'a vintage approach' or a 'batch approach', not unlike wines (Chardonnay 1999 Nappa Valley). This inherent impossibility of perfect standardization poses serious difficulties in the quality control in the manufacturing processes.

The impossibility of identification of active ingredients and impossibility of standardization poses substantial legal risks for both large and small companies. The companies would have virtually no firm scientific defenses. Imagine a situation where so-called company scientists are repeatedly mumbling, "we do not know...we do not know", in the face of serious allegations. Product liability insurances usually cover first few cases only.

In sum, the financial and legal risks are prohibitively high for most companies that are seriously considering producing natural products. Our company was fortunate in this regard. So far, there was no single complaint after the sale of approximate 20,000 units of sale. For us, we believe we have already borne the burden of proof of the safety. Additionally, we have hard data of safety on each ingredient. However, we still acknowledge that if a company is unluckily caught in the legal problem before the sufficient accumulation of cases, there is a huge uncertainty.

### **5-3. Involvement of Chinese and Indian Governments(?)**

One may say that the Chinese government may invest a massive amount of resources to the development of a traditional Chinese medicine prescription for diabetes, supplying a large clinical

study and elaborate lab studies to establish the standardization of a product. Such a scenario is possible, but, very unlikely to actually happen. 1) Standardization and identification problems are not solvable by massive investment. (Do you remember that in infinitely complex systems, the more study you do, the more problems appear?) 2) The Chinese government would not find economic reasons to invest such massive amount of money because the fruits of the investment would not become theirs due to the difficulties in establishing and protecting the intellectual properties. 3) Also, there are already excellent, well known, thus unpatentable prescriptions such as Liu Wei Di Huang Tang. It seems very difficult to find another prescription in traditional Chinese medicine that excels Liu Wei Di Huang Tang in efficacy and safety. If nobody can claim intellectual property on Liu Wei Di Huang Tang, and if the prescription that is being studied is inferior to Liu Wei Di Huang Tang, there is no economic reason to spend millions of dollars to produce it. Likewise, this author finds it very unlikely that Indian government would do something similar, considering the high quality of some of its Ajuurvedic prescriptions. It seems very unlikely that one can come up with any Ajuurvedic prescriptions superior to already well known (thus, unpatentable) Ajuurvedic prescription such as Pterocarpus Marsupium. Knowing that the new prescription cannot beat Pterocarpus Marsupim, there is no economic incentive for anybody to invest substantial resources in establishing scientific standards. It would be re-inventing a new but not so good wheel. In sum, if the Chinese and Indian governments cannot do these kinds of projects that would provide some prescriptions with scientific attributes, there is no way any private company could do this. (By the way, this author truly believes that the above mentioned two prescription should be used as reference points in any study of diabetes treatment, instead of using placebos. This will solve many problems associated with RCT's mentioned in the above. The statistical model this author suggests is that 1) Null Hypothesis: The tested substance is inferior to the above two substances vs. 2) Alternative Hypothesis: The tested substance is superior to the above two substances. )

For the above financial and legal reasons, natural products for diabetes are not likely to be taken up by sizable companies. Even though there are enough legal loopholes in almost all countries that allow some marketing of these natural products, the loopholes are not big enough to allow serious marketing efforts by sizable companies. At the same time, the sheer size of the required investment precludes small companies from entering the market with serious empirical science. Also, quite tragically, as the markets and prestige have been shrinking rapidly for these natural products for diabetes, many powerful prescriptions that have been transmitted generation after generation in the form of closely held family folklore disappear permanently at an alarming speed. Even those that remain often lack the true spirit of the original prescriptions. Sadly, the famous Jewish myth of a King burning the medicine book given by God repeats itself in reality.

#### **5-4. Further Manufacturing Difficulties**

Moreover, there are a few technological difficulties unavoidable in the manufacturing process for these natural products. Most of these natural herbal products have the recommended daily dosage of 10-20 grams. If we are talking about some combination of a few herbs, the daily dosage easily grows beyond 100 grams. Unless certain concentration technologies are employed, the required daily intake inevitably becomes substantially voluminous: 200 units of 500 mg capsules. The technology that concentrates the substance while maintaining the efficacy and safety is extremely difficult and highly costly. Most of the herbal products marketed in North America just encapsule unconcentrated dried herbal powder, resulting in the delivery of only a fraction of required dosages. The realistic chance of those herbal products generating their anticipated efficacy is very small.

As of spring of 2001, however, our main difficulties, still lie in the inconvenience of using the products, which is basically brewing. We have been working on developing liquid forms and other more convenient of our products for the last four years. We wish that we are lucky enough to find other

forms that delivers the same efficacy and safety.

## 6. Conclusions and Practical Suggestions

In the above, some serious shortcomings are pointed out about widely held views of Type II diabetes. The following practical suggestions are made accordingly.

- A) Unless a person is in an acute situation, he should try 'Food and Exercise Approaches', first.
- B) In evaluating natural products, requiring double blind tests, and perfect standardization is absurd.
- C) In terms of efficacy and safety, Liu Wei Di Huang Tang and Pterocarpus Marsupim seem to be excellent choices as treatments for Type II diabetes. If a natural product can be shown to be superior to these two in efficacy and safety, the product must be chosen.
- D) Users should not expect to use a natural product as conveniently as pharmaceutical drugs. They have to be bulky and inconvenient to prepare, often very costly.

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## Endnotes

- [i] Readers interested in this subject may find the following references extremely valuable. 1) James Burke, *The Day Universe Changed*, (Little, Brown and Company 1995), 2) James Burke, *Connections*, (Little Brown and Company 1995), 3) Richard Gordon, *The Alarming History of Medicine*, (St. Martin Griffin 1993), and 4) Porter (ed.), *Cambridge Illustrated History Medicine* (Cambridge University Press, 1996)
- [ii] Gerry Tan and Roger Nelson, *Concise Review for Primary Care Physicians*, Mayo Clinic 1996 gives an excellent review of the subject.
- [iii] Readers interested in this topics will find the following references very valuable: 1) James Gleick, *Chaos: Making a new science*, (Penquin 1988), 2) Mitchell Waldrop, *Complexity*, (Simon & Schuster 1992)
- [iv] Interested readers may look into any introductory econometrics textbook. This author recommends Koutsoyiannis, *Theory of Econometrics*, (MacMillan Press, 1977)
- [v] "Powerful Placebo: The Dark side of the Randomized Controlled Trial," *Lancet* 1998; 1722-1725. Also, his famous book, "The Web That Has No Weaver", professor Contemporary Books, Lincolnwood Illinois, 2000, contains a list of the works of such concerned scholars. pp.380-384
- [vi] Fortunately, there are still a great number of scholars and researchers who would side with the opinion of this author (for examples and list of such scholars, see page 381 of aforementioned "The Web That Has No Weaver" by T. Kaptchuk). For a review of the problems of conventional pharmaceutical diabetes treatments, refer to the aforementioned Tan and Nelson. John Murdoch, *Oral Hypoglycemics*, *Hospital Pharmacy Practice*, March 1994 also provides compact review of the subject.
- [vii] Many practitioners prefer the expression 'complementary medicine' to emphasize that these approaches are compatible with and helpful to the mainstream conventional pharmaceutical approaches.
- [viii] The aforementioned Kaptchuk's book discusses this topic in detail. Also, there have been accumulated studies in this topic. This author's position seems to be consistent with the consensus of most of the researchers of the topic.
- [ix] The names of the products are Eleotin S, Eleotin G, Eleotin M, etc. More information can be found at [www.eastwoodcos.com](http://www.eastwoodcos.com). Also in the appendix of this article.
- [x] For example, R.J. Marles and N.R Farnsworth, *Antidiabetic Plants and Their active constituents*, *Phytomedicine Vol.2*, pp 137-189, 1995 gives a list of more than thousand herbs.

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