Introduction

In November of 1991 one of the world’s most famous athletes, youthful and fit, at the pinnacle of his career, stood at a podium in front of a throng of reporters and announced to world his death sentence. He was going to die. He knew it and now the world knew it. Sports fans and people who never watched a sporting event were stunned. How could this be? The athlete didn’t know the exact date of his death, but it was certain that he wouldn’t live out his full life. If he was lucky, he’d live 10 years. But, maybe he’d die in the next year? No one really knew. It was one of the biggest new stories in the past 30 years.

Anyone old enough to remember Magic Johnson’s press conference announcing that he had contracted HIV can never forget it. He immediately retired from the Los Angeles Lakers, a team with which he had won 5 NBA Championships, 3 NBA Finals Most Valuable Player Awards, 3 NBA Most Valuable Player Awards. A 12-time NBA All-Star with an incandescent smile, the heart and soul of his team who transcended his sport, Magic was now brought low by a virus? Not just any virus. HIV. A killer. It’s difficult to overstate the drama of that moment.

That was 27 years ago. Magic Johnson is now President of Basketball Operations in the Lakers front office and owns part of the team. He lives a full life. He’s got far-flung business interests and is regularly in the media. And, he is the picture of health, possessing the few extra pounds that come with age. He’s well past the point that he was supposed to die. His death sentence was commuted.

Why?

Simply put, advances in therapies for the treatment of HIV have brought the effects of the disease under control. With modern treatment, HIV is no longer fatal. Advanced drug cocktails enable people with the virus to live out a normal life. It’s quite a success story.

If instead of contracting HIV, Magic Johnson had developed diabetes, he wouldn’t be so lucky. The spread of that disease has only accelerated in the past 27 years. And, the treatments haven’t even kept pace, much less advance. In fact, in the last 12 years there have been some 40 new FDA-approved medications come to market for the treatment of diabetes and yet the average level of care is unchanged. On a population-wide basis, the key measure of the control of the disease, HbA1c, is no better now than it was before those 40 new medications hit the market. For most people who develop this disease, it is fatal. It is what we thought about HIV at Magic’s press conference. People may not die as immediately as early sufferers of HIV did, but people with diabetes almost always die from it, though it exerts its influence through other diseases. It robs people of about 10 years of life on average, and the last 5 years of that already shortened life are hardly a picnic.
Diabetes is more than 30 times the problem that HIV was at its worst. While there are about 1 million people in the US with HIV, there are more than 30 million with diabetes. There are also about 80 million with prediabetes, which is really just early stage diabetes. Most of those 80 million will develop full-blown diabetes. The Centers for Disease Control in Atlanta estimates that 1 in 3 US adults will have diabetes by 2030. These numbers are astonishing.

Worse than all that, diabetes is much more of a killer than HIV is now. But, would the public have reacted the same if Magic Johnson had announced he had diabetes?

Diabetes Doesn’t Get Credit

Let’s consider a few recent celebrity deaths: In August of the present year, Aretha Franklin died. It was widely reported that she died of pancreatic cancer. What was not so widely reported is that she was a long-suffering Type 2 diabetic. People with diabetes have a significantly higher cancer risk than non-diabetics. Now, we at Vdex have not treated Aretha Franklin and have never seen her medical records. We cannot say that her cancer was caused by diabetes, but for many cancer sufferers, it is. People with diabetes have a much higher risk of developing all different types of cancer. When those people die, their deaths are not attributed to diabetes, but rather to cancer.

The acerbic comedian, Don Rickles died in April of 2017 of “kidney failure.” What’s the number one cause of kidney failure? Diabetes. Almost nowhere in the media reports about Rickles death did it mention that he had Type 2 diabetes. Can we prove that his renal failure was caused by his diabetes? No, but, it would be naïve to think diabetes was not a factor in his death, if not the major factor.

Last, consider the death of actress Mary Tyler Moore. The Wikipedia entry about her reads,

“She died from cardiopulmonary arrest due to pneumonia at the age of 80 on January 25, 2017.”

While the Wikipedia article does mention Moore’s diabetes, it fails to draw much of a connection between that and the proximate cause of her death. But, as a Type 1 diabetic for 30 years, Mary Tyler Moore very likely died from complications due to diabetes. Or, put another way, without diabetes, she likely wouldn’t have died of what she did, when she did.

Diabetes gets no respect. If diseases were a football team, diabetes would be the offensive lineman: critically important but rarely appreciated. The running back who squirts through the line to score a touchdown is credited. But who opened the hole? When the quarterback drops back and zips a perfect pass to the receiver in the end zone, nobody mentions the lineman who protected the quarterback allowing him the time to make the throw. They talk about the great throw or great catch.
Diabetes has a bizarre image problem. It doesn’t get the credit for being the killer that it actually is. Everybody knows about the disease, but few appreciate its impact. Most people view it as a disease of inconvenience. They view it as something you live with. At worst, you may have to take injections. Otherwise, not that big a deal.

They couldn’t be more wrong.

What the celebrity references above demonstrate is that we’re not focused on the problem, or the inadequacy of the treatments. This failure has led us in the wrong direction. The message of the Magic Johnson story is that there is reason to hope.

**Background**

We at Vdex have long felt this disease could be managed better. Indeed, it must be. The current trajectory of the cost and incidence of the disease is frightful. There are an estimated 450 million people with diabetes in the world and about 900 million “prediabetics.” Those numbers continue to grow. About 1 in 6 people alive today is affected by diabetes. Some populations are far worse. For example, if you meet two Native Americans, the odds are that one is diabetic. If both of those Native Americans are adults, odds are that both have the disease. Native Americans die 15 years sooner than Whites.

The costs of caring for people with diabetes just continues its ascent. In about ten years the cost of the disease in the US will be about $1 trillion annually. As Alfred Mann, developer of the insulin pump and serial entrepreneur in the field of diabetes, described it, “Left unchecked, this disease will bankrupt the world.”

One risks sounding unserious and shrill in discussing the scope of the problem today.

Vdex Diabetes was formed to beat diabetes. We cannot accept that people just succumb to this killer in ever-greater numbers. We felt with some new technologies, the battle could actually be won. One such technology is Afrezza, an FDA-approved, inhaled insulin product manufactured by MannKind Corporation.

In September of 2017, Vdex published its “White Paper on Afrezza Insulin, A 12-month Study.” That document detailed Vdex’ various studies in its effort to better understand the attributes of Afrezza and the best use of the product. Our conclusion was that Afrezza is safe and effective, and superior to other therapies. In recognition of that, we went further to argue for a new treatment paradigm for diabetes. We described that new paradigm as “Afrezza First, Afrezza Instead, Afrezza Always,” more easily referred to as “AFAL” (people in diabetes love to try to come up with clever acronyms). Consequently, Vdex developed its own proprietary AFAL protocols.
Of course dietary changes and exercise are always the first resort to controlling the disease. But, when/if that fails, and some sort of intervention is called for, our protocol was developed to be the guide.

**Chart 1.**

**Understanding Blood Sugar**

This White Paper details the results of treatment of diabetic patients using Vdex’ AFAL protocols. Our reference points for evaluating the success of our treatments were multi-fold: first, we sought to treat patients to achieve blood glucose control consistent with the American Diabetes Association (ADA) recommended goals. Specifically, we set out to bring patients’ HbA1c levels to 7% or less, with minimal hypoglycemia. Recognizing that some 50% to 70% patients fail to achieve the ADA goal with existing protocols, we set out to do better than that. (See Chart 1. above, Understanding Blood Sugar)

As a secondary, aspirational target, we sought to investigate how closely we could manage patients’ blood glucose levels to pre-diabetic levels, defined as HbA1c values below 6.5%. Finally, we set a fanciful, tertiary target of non-diabetic levels, defined as HbA1c values below 5.6%. Could we actually treat people with diabetes in such a manner that they were physiologically non-diabetic while on therapy? If our goal is to beat diabetes, we had to reach for this target. Admittedly, we needed to be careful managing patients to such levels given the concerns about severe hypoglycemia.
HbA1c is a static measure of average blood sugar. We are mindful of Mark Twain’s observation about averages: a man with one foot in a bucket of ice water and the other foot in a bucket of scalding water is, on average, comfortable. To fully appreciate the problem of diabetes one must keep in mind how daily blood sugar fluctuations of people with diabetes compare to non-diabetic persons. The first two figures below illustrate this. The third figure shows what is possible using Vdex’ AFAL protocols.

Typically, with normal, non-diabetic people their blood sugar fluctuates in a fairly tight range from about 70 to 140 (see Figure 1). At a blood sugar level below 50, patients start getting into a dangerous, hypoglycemic condition. At blood sugar levels sustained above 140, patients start experiencing microvascular damage. People with diabetes can see their blood sugar levels fluctuate by several hundred points within a few hours, even if “well-controlled” with medication (see Figure 2). Such people may have a good average (measured by HbA1c), but are subject to possibly dangerous lows (hypoglycemia) and damaging high blood sugar levels (above 140). With the Vdex protocols, patients see much less fluctuation in their blood sugar (see Figure 3) and when properly titrated, can have blood sugar fluctuation that approximates normal function.

![Figure 1 – Daily Blood Sugar Fluctuation of a Non-diabetic Person](image)

The tracings of this diagram illustrate the daily blood sugar fluctuation of a single non-diabetic person over a 7-day period as recorded on a continuous glucose monitor.
Figure 2 – Daily Blood Sugar Fluctuation of a Person with Diabetes
The tracings of this diagram illustrate the daily blood sugar fluctuation of a person with diabetes over a 3-day period as recorded on a continuous glucose monitor. This patient is currently under care for his/her diabetes but NOT USING VDEX PROTOCOLS. The morning spike of blood sugar and the late afternoon/evening rise is typical of diabetics with normal eating patterns.

Figure 3 – Daily Blood Sugar Fluctuation of a Person using Vdex AFAL Protocol
The tracings of this diagram illustrate the daily blood sugar fluctuation of a person with diabetes over a 7-day period as recorded on a continuous glucose monitor. This patient is being cared for USING VDEX PROTOCOLS.

The most important point to make about the figures above is that the highly fluctuating blood sugar levels that define the disease of diabetes are what make it so difficult to treat. As one brings the overall HbA1c level down, which is essentially what basal insulin does, then one increases the risk that the inevitable low points are too low. To successfully treat the disease of diabetes, one needs to flatten the blood sugar curves as they are being lowered.
Observations

In our two years’ worth of experience treating people with diabetes in the very different populations of Espanola, New Mexico and Los Angeles, California, we have noticed some consistent themes. We present these below with the caveat that Vdex is NOT a research organization. We are a diabetes-treating practice. We think this distinction is meaningful for the following reason: as has been cited above, in American Diabetes Association publications and elsewhere, there have been some 40 new FDA-approved medications for diabetes brought to market since 2005, but population-wide HbA1cs are largely unchanged. In other words, despite 40 new tools, the diabetes-treating medical community is not doing a better job controlling average blood glucose. Presumably, each of the 40 new medications showed clinical efficacy. Otherwise, why would the FDA have approved them? Yet, success in the controlled environment of an FDA trial often does not seem to translate into better control with everyday usage. We at Vdex are focused on everyday usage.

The themes below emerged from our observations in every day, real-world use of our AFAL protocols with real patients seeking care. These WERE NOT patients selected for a clinical study. The only qualifier was that the patients had previously failed to control their disease with diet and exercise. We are confident these themes and outcomes are reproducible in other medical practices.

1. Multi-point reduction in HbA1c

Commonly, new diabetes medications are touted due their ability to reduce HbA1c. Reductions of one-half point to a full point, say from 8 to 7.5 or even 7, are meaningful. This is especially true given the oft-cited statistic that for every one-point reduction in HbA1c, there is a 40% drop in damage to the body. Multi-point drops in HbA1c, however, tend to be uncommon.

In our experience we have routinely seen multi-point reductions in HbA1c. It is not unusual for a Vdex patient to drop 4 or 5 points, for example from 10 to 6. The highest HbA1c we’ve seen is 18.1 and presently this patient’s HbA1c is below 10 (and heading lower).

This experience has been more common in the New Mexico patients who are more poorly controlled than those we’ve seen in Los Angeles. Certainly, starting at a higher HbA1c permits more multi-point reductions. But the salient conclusion is that use of insulin, specifically Afrezza insulin, is far more effective at controlling blood sugar than other medications.
A subtler explanation for the multi-point reduction in HbA1c is the fact that Afrezza is a prandial insulin as opposed to a basal insulin. As such, used properly, Afrezza targets and very effectively blunts the post-prandial glucose excursions that are so common in people with diabetes. Because of its speed, Afrezza effectively preempts the high post-prandial glucose levels that one sees even with the use of injected prandial insulins, so-called rapid-acting analogs RAAs, and it is those levels that disproportionately contribute to high HbA1c. HbA1c is just an average blood glucose level. In effect, the really bad data in the HbA1c calculation is the post-prandial data. Take out the bad data and you get a much larger effect on the average. This is very well demonstrated with the blood glucose charts contained in Figure 4. below.

This patient came to Vdex under the care of another physician using traditional tools to control his diabetes. The data in this chart is aggregated over a 14-day period rather than displayed as individual daily tracings. The thin, dark blue line is the median data. The dark gray area is the range of the 25th to 75th percentile of the data and the light gray area represents the 10th to 90th percentile of the data.

In the upper chart, the patient’s starting HbA1c is 10.8. Note that the patient’s blood sugar begins to rise in the afternoon around about 2:00pm and skyrockets to well above 300 mg/dL until it begins to come down around 10:00pm. This particular patient consumes most of his food in the afternoon/evening period. His blood sugar control is very poor, and will absolutely lead to long term damage to his body.

Our treatment strategy was to reduce the afternoon blood glucose excursion using our protocols. The results are dramatic. In the lower chart, one can see that the afternoon/evening excursion has been eliminated. As a result, the patient’s HbA1c has been brought down to 6.3, a huge reduction for any patient.
Figure 4. Elimination of Post Prandial Excursions
Through the use of the Vdex Protocols, this patient’s post prandial excursions are reduced and his HbA1c is very significantly reduced. His blood sugar fluctuation is much reduced.
2. Speed of Reduction

Related to the point above, we have achieved multi-point reductions in HbA1c very rapidly. For context, it is important to understand that the typical diabetes-treating medical practice sees patients every three months. So, the HbA1c improvement of a patient, if any, occurs over a period of many months or years. This has many, predictable disadvantages. At Vdex, we intensively manage patients so as to achieve very significant improvement in weeks, not months. Consider Figure 5 below, which graphically illustrates the results from three actual patients. The first, illustrated by the red line, saw his HbA1c fall from 10.8 to 7.4, a drop of 3.4 points, in two weeks. Another patient’s HbA1c (blue line) came down from 14 to 6.7 also in two weeks. A third realized an improvement of 7.5 points, from 13.2 to 5.7 in one month. These are not outlier results. They are the norm. The dotted line represents a hypothetical patient starting with an HbA1c of 12 and the expected improvement over the course of treatment. Changes of this magnitude are simply not happening with conventional therapies today, and certainly would not happen this quickly.

**Figure 5.**

**Course of Treatment with AFAL Protocol**
We are confident in our dosing protocols based on our experience. Those protocols are more aggressive than what we followed initially, given our comfort with the safety profile of Afrezza (discussed in more detail below). Consequently, our initial dosing of patients is higher and patients see results more quickly.

One other point needs to be mentioned: we have observed a very broad safety margin with the use of Afrezza that further supports aggressive dosing and more rapid results. For example, if a patient needs a 8-unit dose based upon his level of insulin resistance, and instead takes an 12-unit dose, there is little chance of trouble. He is not likely to even notice the difference. If there is some symptomatic hypoglycemia, it will be mild and transitory. Such would not likely be the case with use of injected, rapid acting analogs. We believe this difference between Afrezza and RAAs is due to the hepatic sensitivity that occurs with Afrezza and that seems to be absent with the RAAs.

It’s important to put these first two themes into context. Almost every patient who comes to Vdex is under the “care” of another physician and is usually seriously uncontrolled. We are able to improve every one. Also, since diabetes is a 24 x 7 x 365 disease, most of the management of the disease is done by the patient. So, analogizing to shooting a basketball, we are able to teach patients to shoot very well, very quickly. An HbA1c drop of 1 point would be like shooting baskets from the free throw line. A drop of 2 points would be like a shot from the top of the key. 3 points would be a half-court shot. A reduction of 7 points is like making a shot across 3 courts. We can teach patients to do that in a few weeks.

3. Hypoglycemia experience

To date, with over 200 patients treated, we have yet to observe a single, severe hypoglycemic event. This is unheard of with the use of traditional insulin, especially when one considers the low levels of HbA1c we achieve. Part of the reason that the ADA target for HbA1c is set higher than the point at which microvascular damage occurs is due to the unacceptable level of hypoglycemia that happens as one lowers HbA1c.

As an aside, we define “severe hypoglycemia” as hypoglycemia requiring the intervention of a third party to correct. Some patients who’ve had rapid, multi-point reductions in HbA1c have reported symptoms associated with hypoglycemia, even though their blood sugar was not in the range of hypoglycemia. Such symptoms were relatively transient, lasting several minutes and definitely less than an hour. With continuous glucose monitors (CGM), we’ve been able to actually observe patients’ blood glucose levels and have seen this phenomenon occur in patients with blood sugar levels well above 100. Most important, these patients did NOT need any help in dealing with the temporary “low” blood sugar experience.
Type 1 patients seem most prone to hypoglycemia due to their basal insulin. This seems even more pronounced with the newer, longer-lasting basal insulins. With the Vdex protocol, we often have to reduce the basal insulin dose. Logically, prandial blood glucose control is the greater challenge for people with diabetes than basal control. Meals are when we take in large amounts of carbohydrates that cause blood glucose levels to spike. It has been our experience that if one attacks the prandial need aggressively, then the basal need is quite low.

Given the history of hypoglycemia related to the use of insulin, the obvious question is why don’t we see that in our patients? After all, we’re managing our patients with Afrezza and Afrezza is insulin. We believe the answer is due to the unique qualities of Afrezza insulin. To start with, Afrezza is the first and only truly physiologic insulin. It is the same molecular structure as what the body generates and employs. All other insulins in the world are synthetic, and not of a natural, usable molecular structure. The human body must convert those other insulins into a usable form. This accounts for the different action in the body. In Figure 6. below you see the action of Afrezza insulin as compared to normal pancreatic insulin and “RAAs” (rapid-acting analogs) which are the current gold standard of prandial insulins. It’s obvious that Afrezza is near perfect match to normal pancreatic insulin. RAAs don’t peak as quickly and linger too long in the body. It is this mismatch between RAAs and normal function that leads to problems like hypoglycemia.

**How Afrezza Insulin compares to Healthy Nondiabetic Insulin response**

*(The RAA curves are a graphical approximate representation of data stemming from several studies.)*

![Figure 6. Pharmacokinetics/Pharmacodynamics of Afrezza, RAAs v Pancreas](image-url)
The natural action of Afrezza leads to a host of salutary benefits, most important of which is a far lower risk of hypoglycemia. What one sees in the blood sugar curves in patients taking Afrezza is a flattening of those curves. The amplitude being lower, one can lower the overall curve without the risk of going too low. A good example of this is exhibited in Figure 7 below. These are the same charts as we used earlier in Figure 4 above.

Despite such a large drop in HbA1c, 4.5 points, one can see that the patient’s average blood sugar for the period (dark blue line) never drops below 80. Even the lowest curve for the period, illustrated by the light gray curve, barely drops below 80. These are far from dangerous blood glucose levels.

Figure 7. Flattening of BG Curves with Use of Afrezza
We present below in Figure 8, another good example of this phenomenon. This patient has a starting HbA1c of 6.5. This is considered excellent and most physicians would refuse to alter anything about his treatment. They’d feel there’s nothing to improve and treating such a patient could only make him worse, or risk hypoglycemia. However, evaluating this situation candidly, one would have to admit that the HbA1c is above normal. We sought to improve this patient and followed our protocol, the results of which are illustrated in the lower chart. His HbA1c is now 5.5. Further, despite dropping his average a full point, there’s no hypoglycemia.

**Figure 8. Flattening of Blood Glucose Curves in Well-Controlled Patient**

With a HbA1C of 5.5 the patient above is physiologically non-diabetic. In other words, this patient is unlikely to have microvascular damage and therefore, unlikely to have complications from the disease.
A greater emphasis on prandial control, and hence use of prandial insulin, flies in the face of the ADA recommendations for Type 2 patients that call for the first use of insulin to be a basal insulin. The ADA recommendations were developed based on the tools available. Since basal insulin was safer than prandial, it was logical that this would be the first insulin recommended. Today, we have better tools. As noted above, our experience with Afrezza negates the safety concerns and argues strongly for use of Afrezza as first therapy for diabetics. One would simply not attempt what we did with the well-controlled patient, using the current ADA protocols.

4. Persistence/Stability of Effects

With conventional treatments, patients can gain some temporary control of blood sugar, but in the usual course, control eventually wanes as the disease progresses. HbA1c gradually rises and patients are then prescribed additional medications on top of what they’re already taking. In time, many patients, perhaps most, will progress to injectable medications like GLP-1s, and then insulin. They might be taking 3 – 4 oral medications at the same time.

![Figure 9. Illustration of Hypothetical, Complex Drug Interactions](image)

One can only guess what effects might flow from all the potential drug interactions over the long term. It is simply impossible to study all the possible chemical interactions.

In our patients, we have had a very different experience. We not only bring their HbA1cs down, we keep them down. We have one primary tool in our AFAL Protocol: Afrezza. In most cases, we see no need to augment the Afrezza dose with additional agents. In fact, we slowly titrate most patients off their other medications (see further detail on this point below).
We have only studied patients for approximately 2 years, so we cannot say with certainty that they won’t show disease progression in later years. But, this seems unlikely. We know that our protocols relieve stress from the pancreas. Studies suggest the pancreas could regain some function with continued use of Afrezza. At worst, we expect no more progression of disease.

5. Patient reaction – compliance

Patients’ reactions to, and compliance with, the Vdex AFAL protocols have been consistently good. We are aware that this is a departure for many patients with diabetes. We’ve heard the comments from other providers about the generally poor compliance of many diabetes patients, and in particular, those patients whose disease is out of control. In fact, the former begets the latter.

We expected compliance to be higher at Vdex for the obvious reason that with our protocols, there are no more prandial injections. For most of our Type 2 patients, we can eliminate injections altogether.

Further supporting the compliance of patients with the Vdex protocols, are the effects that patients report. From the moment they start on the protocols, virtually 100% of patients comment that they sleep better. People with diabetes routinely awaken multiple times each night to use the bathroom. Frequent urination is often the way it is with this disease. Soon after starting on the protocol, Vdex patients report that where previously they were going to the bathroom multiple times per night, they now only get up once. We proudly recall several comments from patients such as the email copied below.
first nite in probably TEN YEARS where I did not get up in the middle of the night to pee...literally 10 years...no joke.

Bob S.

As we eliminate some of the other medications, patients feel better too. One good example is metformin. Many of the poorly-controlled patients have been taking the maximum daily dose of metformin, 2000mg. At this dosage, a considerable segment of the patient population, perhaps 40-50%, have gastrointestinal problems: diarrhea, gas, nausea. At Vdex, we routinely eliminate metformin from the therapy.

### 6. Simplification of therapy

It has long been recognized that insulin is the most effective way to control glucose levels; it is the way the body does so naturally. But traditional insulin usage has been associated with many problems, not the least of which are: injections, difficulty of dosing properly, the risk of hypoglycemia, increased blood sugar testing, poor compliance, etc. None of these issues with traditional insulin applies to Afrezza. At Vdex, as we introduced Afrezza we initially did not alter the patients’ prior therapy, other than to substitute Afrezza for any other prandial insulin the patient was using. As we achieved greater control for the patient, we then began to reduce, then eliminate, other medications the patient was taking. This simplification of therapy has been well received by patients.
As we eliminate other medications, we not only eliminate their side effects which are considerable in some cases, but we also reduce the cost of care. Some of the newer medications, like the SGLT2-inhibitors for example, are patented products that are also quite expensive. We find that we achieve greater blood sugar control even after eliminating them entirely, with greater predictability.

**Conclusion**

At this writing, we have treated more than 200 patients with our protocols. The themes described above have been remarkably consistent. Further, the results attendant to each theme have exceeded even our most hopeful expectations. We have managed patients from very high HbA1c levels into a normal range without seeing ANY severe hypoglycemia. With our protocols we have seen most patients with HbA1cs below 7 and many into the 5s. A few reached the high 4s. None has had problems with hypoglycemia. For many patients, the Vdex AFAL protocols literally result in total control over their disease, control that renders their diabetes a mere nuisance rather than the killer that it usually is.

We strongly encourage readers to pause and reread that last sentence. We submit that short of a cure, this is the best possible outcome.

The American Diabetes Association recommends a target HbA1c of 7% or less. This is the current standard of care. Yet, it is known that microvascular damage begins at much lower levels, about 6.2. Managing the disease of diabetes by these standards is just managing failure. It’s difficult to conceive otherwise about the present-day treatments when they still shorten life by about 10 years and result in monstrous complications like blindness, kidney failure, amputations and heart disease, to name only a few. Isn’t this really like the death sentence that HIV sufferers faced in the 1980s?

The problem is the tools being used.

Given the limitation of the available tools, doctors are doing the best they can. The ADA recommendations make sense. The technology employed in the Vdex protocols shows there’s a better way. We have better tools.
At Vdex, we find ourselves at the dawn of a new age in the treatment of the world’s most prevalent disease. We are quite confident about being able to avert many of the long-term complications of diabetes that are so disruptive to peoples’ lives and so horribly expensive to treat. We need to intervene in the management of the disease at an earlier point. In fact, we argue for the diagnosis of diabetes at an HbA1c of 6.2 rather than 6.5. We need to keep blood sugar from ever going out of control; We need to bring all patients down to an HbA1c of 6.2 or less. It is at this point that we go from managing the decline of patients to truly controlling their disease. As many Vdex patients have told us, “Now, I control my diabetes; it doesn’t control me.”

We go further to say that with early intervention at the stage of “prediabetes” (a terribly misleading term), we strongly suspect we can prevent a patient from ever developing full-blown diabetes. At the prediabetes level patients still have good pancreatic function though the organ is clearly stressed. Our experience suggests that our protocols will relieve stress from the pancreas, prolonging normal function and likely restoring some lost function. Such patients can live full, productive lives with a minor assist to control their blood sugar.

As always, diet and exercise should be the first option to control the disease. Our suggestions presume that has been tried and failed.

So, consider, we can now change the course of this horrible disease. We can bring it under control. What are we waiting for?

The claims of this White Paper are quite bold, we realize. Our AFAL protocol is revolutionary. But, the conclusions of this paper are not so much Vdex’ opinions as they are positions to which the data from our experience has driven us. In a very real sense, our position is inevitable. Any honest assessment will lead to this point.

This is a 180-degree change for the field of diabetes. Where the current recommendations call for use of insulin as a last resort and basal insulin as the first insulin used, we’re arguing for insulin as the first resort and a prandial insulin at that. We’re arguing that the current recommendations are exactly the opposite of what they should be. Surprising? Crazy perhaps?

We suggest stepping back and comparing this proposed revolution to the one that saved Magic Johnson’s life and millions of others’ lives. In some ways, it shouldn’t really surprise us at all.

Isn’t it about time this happened?
Disclaimer

We restate the disclaimer from our first White Paper. All readers should be aware that some of the people associated with Vdex, who also participated in some of the studies, are shareholders of MannKind Corporation. None works at, or is compensated by, MannKind Corporation, however. **We present this disclaimer so readers will be aware of the potential for bias in the results presented.** Vdex receives no compensation for prescribing Afrezza from any source, and no compensation from MannKind Corporation for its research or conclusions, nor has anyone associated with Vdex ever received any compensation from MannKind. We were neither guided, nor advised by MannKind Corporation in the development of our protocols, or our prescribing behavior. The company was completely unaware of how we used their product.