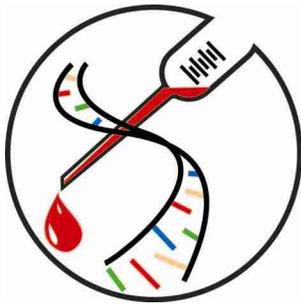
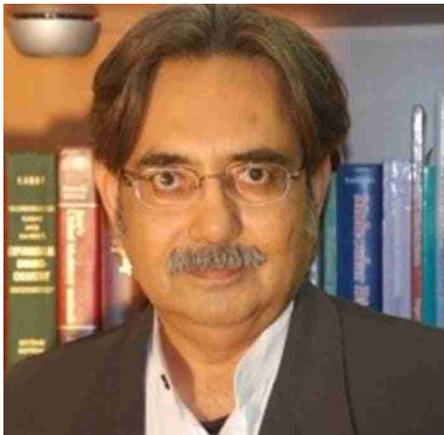


Changing the Standard of Care for Diabetes Management, Monitoring and Diagnosis, Epinex Diagnostics, Inc. is developing a Test for Measuring Glycated Albumin that will help up to Ninety Five Percent of Diagnosed Diabetics through Monthly Self-Monitoring and Millions of Undiagnosed Diabetics through Simpler Screening



**Healthcare
Diagnostics**



**Asad Zaidi
CEO**

BIO:

Asad R. Zaidi, President & CEO is a biochemist and biomedical engineer who graduated with honors from University of California, Irvine. He has been involved with the development of heart valves, artificial coronary arteries, membrane oxygenators, dialyzers and various in-vitro-diagnostic and biomedical devices since 1973. His experience of over 25 years spans the growth of biomedical devices in companies such as Shiley

(Pfizer), C.R. Bard, Mitral Medical, Bicer Medical, and Medtronic. He has been responsible for licensing and transferring medical device manufacturing technology from Latin America to Canada and to England. His areas of expertise range from product development to patenting and production. He has written and assisted in FDA submissions of 510k pre-market notifications, investigational device exemptions (IDE), and pre-market authorizations (PMA).

About Epinex Diagnostics, Inc.:

Epinex is founded on the principle of applying expert scientific knowledge and proprietary technology for the benefit of users and the healthcare system. We are dedicated to advancing the technology of rapid diagnostics in order to provide easy access to critical diagnostic information at low cost. Our goal is to enhance patients' quality of life with diagnostic tests at the office, point of care, and over the counter to reduce costs, alleviate patient anxiety, enable earlier therapeutic intervention, and improve patient outcome.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Mr. Zaidi, what is the vision and focus at Epinex?

Mr. Zaidi: Epinex is going to change the standard of care for diabetes management, monitoring, and diagnosis for years to come. We are developing a test that will help up to ninety five percent of diagnosed diabetics control their diabetes through

monthly self-monitoring, and provide millions of undiagnosed diabetics better and simpler screening and diagnostic testing. In short, we are shifting the paradigm of how Type 2 diabetes is diagnosed, managed, and screened.

CEOCFO: What are you testing for? How does it differ from the tests that are currently available?

Mr. Zaidi: We are testing for damage caused by excess sugar to albumin, which is the human body's most abundant circulating protein. When there is too much sugar in the blood, the sugar attacks the albumin molecules and changes its normal properties and functions. This is called glycation. What we are testing through the measurement of glycated albumin, is the actual amount of protein. By measuring the amount of damage on a monthly basis, a diabetic can track how well he or she is managing the condition and can make adjustments to improve their health.

It is different from the existing tests in that it is like a monthly report card. There are only two methods available now. One is self-monitoring blood glucose measurement, SMBG, where people prick their finger usually many times per day to find out how much sugar they have in their blood. However, knowing how much sugar you have at a given moment does not tell you whether you are diabetic or not, and more importantly, knowing how much sugar you have at a given time does not tell you how much damage that sugar has done to the proteins in your body. You see, it is actually the

damage that sugar does to proteins like albumin that contributes to diabetes complications, such as nephropathy, retinopathy, and neuropathy. Diabetes is the leading cause of kidney failure and blindness in American adults and is the leading non-accidental cause of amputations. The other test available is called Hemoglobin A1c. A1c testing is currently the gold standard for diabetes management. This test tells you how much sugar has gotten inside your red blood cells. But because of the life cycle of red blood cells, which mature over one hundred and twenty days to two hundred and forty days, the A1c test can only tell you what happened to you three to six months ago. So if someone with diabetes or pre-diabetes goes to their doctor and the doctor gives them this test and the result is high, the doctor says, we have to treat your condition, but it has already been going on for months.

CEOCFO: Has it always been known that measuring changes to albumin was a way to measure glycation? Are you the first to measure this, or have you found a way to make this more workable?

Mr. Zaidi: Research in the laboratory on glycated albumin as a marker for diabetes goes back more than 30 years. Many researchers have studied glycated albumin, mostly in Japan and China, and they have found that glycated albumin is a better marker for diabetes monitoring and diabetes assessment than current tests. However, the test could only be done in the laboratory. We are making this monthly test readily available to the doctor's office at the point-of-care and to the general public as an over the counter device, like the glucose meters we have today.

There is mounting evidence that SMBG testing isn't of much value, particularly for Type 2 diabetics who are non-insulin dependent. The Centers for Medicare and Medicaid Services, which manages government programs like Medicare, is consider-

ing whether to cut back on payments for blood glucose testing for Type 2 diabetics because major studies have shown it isn't effective. The same thing is also happening in England and other places around the world. Our test will allow people to test themselves once a month, and if the data shows a positive trend then they will not have to prick their fingers many times every day for the blood glucose test.

CEOCFO: How is the test done? Is it a blood test?

Mr. Zaidi: It is a blood test that is done in a very simple way. You take a drop of blood and put it into a small collection vial. You shake it up, drop this sample into a test cassette and within five to ten minutes you will have the results. You will get an in-

"As many as forty percent of our youth are going to become obese and eventually turn into diabetics. What are we as a nation going to do about it? If we keep our eyes closed and ignore this situation, things will continue to go the way that they are going and diabetes will continue to rise. However, with the emphasis on preventative care, the change is actually coming. Doctors are now going to be forced to think more about preventative medicine than treatment down the road. It is actually happening." - Asad Zaidi

dexed result, which is a proprietary index that we are developing called the G1A™ and it measures your total albumin and your glycated albumin. Combining the two measurements into a single index compensates for other factors such as age, sex, height, and weight and gives a result that will tell you where you are on the scale for [managing] diabetes.

CEOCFO: What is the range of accuracy?

Mr. Zaidi: We have not released the index yet, because we have not released the product to the market. However, the accuracy will be the same as you would find in the laboratory. We are developing the test to make sure that it is accurate, sensitive and that it complies with the current standards that clinical laboratories have.

CEOCFO: Where are you in the development process?

Mr. Zaidi: We are in the process of doing correlation studies with large numbers of samples. We are getting our raw material characterized to make sure that we can produce the test in mass quantities. We have done a lot of scientific research to understand how albumin behaves and how sugar attaches itself to albumin. In terms of where we are, as you know small companies are continuously looking for funding. We have raised all of our own capital so far and have not at this point received any funding from broker-dealers or venture capitalists. That has been a stumbling block in making the test available. However, we have decided to continue to do this project on our own and hopefully, if everything goes okay, and we are able to meet our financial requirements, we will apply for FDA approval within six to nine months.

CEOCFO: You mentioned that people could know that they had diabetes early on or that doctors could test early on. Do you see that as more of the market than people that currently have diabetes? Or is your technology applicable in both

cases?

Mr. Zaidi: Our technology is applicable for both situations, to help people control their diabetes and to screen large numbers of people to see if they are diabetic or pre-diabetic while it is at an early stage. For example, a few months ago, the Japanese Red Cross published a study about their results from performing glycated albumin testing on all blood donors. They tested 3.1 million people for glycated albumin and they were able to show that telling people their glycated albumin score changed people's behavior and helped them make healthier choices. The idea is that, here you have a large captive audience of seemingly healthy, normal people that you can easily screen and hopefully prevent them from developing diabetes. The results were amazing. The people they tested who had elevated

levels of glycated albumin and shown to be at risk of getting diabetes were informed of the risk, and educated about what they could do. The Japanese are very conscientious people; they regularly donate blood, so when they retested the same people when they donated blood again, the researchers saw that about 60% of the at-risk donors had decreased glycated albumin measurements.

CEOCFO: How will you make inroads into an industry where lots of testing already exists?

Mr. Zaidi: Our test will allow people to check their diabetes status once a month, which will cause a lot less pain and inconvenience and cost a lot less money than multiple daily glucose tests. At the same time, they are getting more immediately relevant results than the A1c test; which is done every 3 to 6 months. Our main challenge is professional or medical inertia or stasis; the reluctance of the medical community to change and adopt new practices. However, change in the medical industry is happening right now. ObamaCare has become a reality. Parts of the Affordable Care Act are already being implemented. There is a very conscious effort on the government to emphasize preventive medicine more than treatment-based medicine. They would rather pay to prevent people from needing an amputation than to pay much more to have the surgery for amputation. The government has created the National Prevention

Council that has come out with guidelines and a strategy for public health, disease prevention, early detection and diagnosis, with special attention in the area of obesity. Type 2 diabetes is being diagnosed in younger people at increasing rates and this is being blamed on the obesity epidemic. There was a recent article in the LA Times about the direct relationship between soft drinks and diabetes and obesity. Another one that just came out mentions that as many as forty percent of our youth are going to become obese and eventually turn into diabetics. What are we as a nation going to do about it? If we keep our eyes closed and ignore this situation, things will continue to go the way that they are going and diabetes will continue to rise. However, with the emphasis on preventive care, the change is actually coming. Doctors are now going to be forced to think more about preventive medicine than treatment down the road. It is actually happening.

CEOCFO: What are the next steps? What is going to happen in the next six months to a year at Epinex?

Mr. Zaidi: We are continuously wooing investors and continuously looking for partners and looking to make alliances similar to the one we have with a large pharmaceutical company from Korea that has made a substantial investment in Epinex. But US investors have been rather coy. We have not yet gotten any traction with major US investors and financial institutions.

However, what we are doing resonates with the general public, with individual investors, and those people are the lifeline of our company. We have friends, family, and acquaintances who have invested in this company for almost seven or eight years now, and they are waiting for us to complete our mission. What is going to happen? We are hoping that our financial situation will improve and boost our ability to continue development of this test and get it into manufacturing. With full funding, within six months we should be able to submit our test for regulatory approval.

CEOCFO: Why does Epinex stand out?

Mr. Zaidi: We are the only company that is going to put in doctors' hands and eventually in diabetics' hands a device that will enable them to know how well they did last month compared to previous months and to know what needs to be done in order for them to manage their diabetes. We will be the only company to have a rapid test that will help people easily find out if they are at risk for diabetes before possible complications have had months to cause damage. We have the patents on it. Our IP is very well secured. There are more than 600 million diabetics and pre-diabetics in the world and it is increasing at an alarming rate. We believe that there is a huge market for glycated albumin testing.



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