



DIABETIC INVESTOR

The BGM Market – A retrospective analysis, How did things get so bad?

Now that all the major blood glucose monitoring companies have reported their results for their most recent quarter, it's safe to say that the BGM market is in the final stages of transformation. Sales are down, test strip usage remains where it was 10 years ago, all the major players have initiated major cost cutting measures and it's doubtful that the future offers much hope of a turnaround. How is it possible that a market once growing at mid-double digit rates has fallen so far so fast? How is it possible, when the patient population is growing at epidemic rates, sales of monitors and test strips are NOT increasing? Why is industry consolidation not only a foregone conclusion, but essential? Finally, given market dynamics, where will the market be 10 years from today?

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Looking back, this failure to create value began in the 80's when Bayer became the first company to give away monitors for free. This strategy was perfectly understandable given the dynamics of the business, where the real money is made from continuing sales of test strips. All Bayer did was apply the razor/razor blade business model to blood glucose

monitoring. Bayer correctly reasoned that patients provided with a free monitor would use the monitor on a regular basis. What Bayer and the many companies who followed Bayer's lead failed to anticipate was, in the eyes of the patients, the monitor was the prime component in the process, not the test strip. This is exactly opposite of the business aspects of BGM, where the real technology is in the test strip, not the monitor.

This move towards providing free monitors also created several unintended side effects. Since monitors were free, many patients believed that regular monitoring wasn't all that important since the

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device they used to perform this test was free. Secondly, the availability of free monitors encouraged frequent switching between systems. Because everyone was giving away free monitors, this created a new problem for BGM companies: the need to differentiate their systems from the competition.

painful and more patient friendly. This move was the beginning of a technological arms race and to a great extent diverted attention away from an issue that now haunts the entire industry: patients don't understand the value of the information provided by these systems.

While no one could argue that

this fancy technology.

As companies introduced even more sophisticated monitors with a host of fancy features, it became increasingly difficult to differentiate products. This, in turn, led companies to spend millions on direct to consumer advertising and soon the airwaves were full of ads

The evolution of glucose monitoring technology - We've come a long way, unfortunately even with the many improvements in glucose monitoring technology average testing frequency remains dismal.



advancements in technology such as smaller blood samples, faster test results, alternate site testing and no-coding did not benefit the patients, these advancements had two major drawbacks. First, companies quickly copied each other fearing that if their system was not state of the art, they would lose valuable market share. Second, in their quest for ever more sophisticated technology, no one bothered to ask the patient if they wanted all

Photo's Courtesy of www.mendoza.com, LifeScan, Animas, Bayer and Dexcom

from glucose monitoring companies. This move towards direct to consumer ads was the first step towards the market shifting from a medical device market to a consumer product market and eventually to where it stands today - a commodity market.

Looking for ways to differentiate themselves from the competition, companies began investing heavily in technology. The goal was simple: make glucose monitoring less

Yet, with every technological advancement or strategy shift by the BGM industry, one fact went largely overlooked: average testing frequency didn't increase. This fact, although well known throughout the industry, was ignored as the market was growing at mid-double digit rates. Perhaps lulled into a false sense of security by the rapid market growth, companies believed things were just fine. They probably reasoned that although average testing frequency was not increasing, the epidemic growth rate of diabetes would provide them with a continuing supply of new customers.

Based on earnings reports from the various companies in the BGM market, growth began to slow as we moved into the new century. Given that new technologies and slick ad campaigns weren't working as they had in the past, the industry turned to another time tested strategy – when all else fails, buy market share. After Johnson and Johnson (NYSE:JNJ) acquired Inverness Medical Technology's diabetes care business for \$1.3 billion in May of 2001, Abbott (NYSE:ABT) went out and bought upstart Therasense for \$1.2 billion in January of 2004. While JNJ's acquisition had more to do with gaining control over costs, Abbott's acquisition was clearly designed to build market share.

About the same time that market growth was slowing, a new problem emerged. Several studies were published that called into question the value of regular glucose monitoring for non-insulin using patients, by far the largest percentage of patients with diabetes. Instead of aggressively fighting the results of these studies and demonstrating the value of regular moni-

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toring by this patient group, the industry, by and large, ignored the studies. Once again, the industry had an opportunity to create value for their products and failed.

With market growth slowing and old strategies failing, it was just a matter of time before the industry resorted to the most tested strategy of all to grow: discounting. While discounting had always been a part of the market, this tactic reached new heights when Abbott began offering aggressive price concessions in an attempt to gain market share. This was the last thing the market needed and was in some ways the beginning of the end. The fact is, once price became the primary weapon to gain market share, the market was in the final stages of transformation. From this point forward, the BGM market would no longer be a medical device or consumer product, but a commodity market.

Just as they did with free monitors, slick marketing campaigns and technological advancements, all of Abbott's competitors matched Abbott's price cuts, effectively surrendering control of the market from the people who make the products to the people who buy and distribute the products. The fact that Cardinal, one of the larger distributors, felt comfortable removing Abbott products because Abbott was unwilling to meet Cardinal's price demands, and then Abbott's subsequent decision to meet these

demands, is a perfect illustration of how the market has forever changed.

It should be said that not every company in the market ignored the changing dynamics of the market. With market growth slowing and the cost of acquiring new customers increasing, LifeScan, a unit of Johnson and Johnson, changed tactics and began an all out assault on capturing patients using insulin. Unlike non-insulin using patients who do not need to know their glucose levels before taking their medications, patients on insulin therapy must have this information so they can properly dose their insulin. The biggest fish in the insulin using pool are patients using an insulin pump who, on average, check their glucose levels 8 times per day. While insulin pump patients are a mere fraction of the 24 million patients with diabetes, they account for almost 25% of all test strips sold.

Besides going out and buying insulin pump maker Animas, LifeScan signed an exclusive deal with insulin pump market leader Medtronic (NYSE:MDT) to provide a monitor that communicates with the MiniMed line of insulin pumps. (Exclusivity applies to the MiniMed US business while Bayer captured the rights for non-US business. It should be noted that

two-thirds of all pumps are sold in the US.) LifeScan also went out and bought the Children with Diabetes (CWD) website, which was the leading diabetes website. With its long and distinguished history, CWD had a strong track record of reaching insulin using patients. It wasn't long before LifeScan overtook Roche as the market leader for glucose monitoring in the US and narrowed the gap between them and Roche globally.

LifeScan should be given credit for developing and executing a strategy that effectively dealt with the changing dynamics of the market as well as positioning the company to deal with the future; a future that will see continued pricing pressure, which in turn will produce lower margins, which in turn will produce smaller, leaner BGM companies. However, pricing pressure won't be the only force driving the BGM market.

GLP-1 Therapy

Although non-insulin patients rarely monitor their glucose levels on a regular basis, they do outnumber insulin using patients by about an 8 to 1 margin. It would seem logical that any company that successfully captured even a small percentage of this huge market would be well positioned for the future. That may have been true before the advent of GLP-1 therapy, but is no longer true. GLP-1 therapy has the potential to be a paradigm shifting technology and could lower test strip usage by another 20 to 30%. Unlike insulin, patients in GLP-1 have no need to monitor their glucose levels as GLP-1 therapy is not dose dependent. Patients take the same dose of GLP-1 regardless of their glucose levels. Given the strong profile of GLP-1 therapy and newer options which are administered just

The blood glucose monitoring market faces changes that go beyond price. New drugs such as Byetta® and Victoza® will soon emerge as the dominant therapy option for patients with Type 2 diabetes. Unlike insulin therapy patients using a GLP-1 have no need to monitor their glucose levels. Additionally as reimbursement improves a greater percentage of insulin pump patients will be using a continuous glucose monitoring system that communicates with their pump further cutting into strip usage.



once-a-week, Diabetic Investor anticipates GLP-1 therapy becoming the predominant option for treating Type 2 diabetes.

Continuous Glucose Monitoring

While the FDA has yet to approve any CGM system as a replacement for conventional glucose monitoring, there is no question that as these systems improve and become more widely reimbursed, they will negatively impact test strip usage among insulin pump patients. As stated previously, insulin pump patients are the most coveted patients for BGM companies. It is also true that insulin pump patients are using CGM in ever greater numbers. Already, Medtronic has a CGM system that communicates with their pumps and Dexcom (NASDAQ:DXCM) is working with



Photo's Courtesy of Amylin, Novo Nordisk and Medtronic

Animas and Insulet (NASDAQ:PODD). In the very near future, Diabetic Investor anticipates that 40% of insulin pump patients will also use a CGM system. Although they will still need a conventional monitor to calibrate their CGM system, Diabetic Investor sees test strip usage falling another 10 to 15%.

Health Care Reform

It is no longer a question of if we'll see healthcare reform, rather just what will healthcare reform look like. Still, with all the talk

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about healthcare reform, the real issue is the rising cost of healthcare and who pays for it. It would be great if healthcare reform was really about preventative medicine and helping patients more effectively take control of their health and wellness, but this ignores the realities of our current healthcare system. The fact is physicians are not paid to prevent diseases, they are paid for treating them. Nor are physicians paid to educate patients so they can take better control of their health and wellness. When it comes to healthcare reform, it's all about controlling or lowering costs.

This does not bode well for any chronic disease state and diabetes in particular. Already we have seen health insurers raising co-payments for glucose testing supplies as they look to shift more of the cost to the patient. Add in the studies calling into question the benefits of testing for non-insulin using Type 2 patients, and it won't be long before insurers only reimburse patients on insulin therapy. This would add just one more nail in the coffin for the Type 2 market.

Value Systems

One of the few beneficiaries of these changing market dynamics are companies like Home Diagnostics (NASDAQ:HDIX). Unlike the major branded companies, HDI produced monitors are marketed and branded by retailers and drug wholesalers. This allows

The day is quickly coming when retailers will feature fewer brand name monitors and more aggressively market their store branded products. Store branded systems offer two critical benefits over branded products, higher margins for the retailer and increased store traffic. In the eyes of the consumer they can get test strips for branded products anywhere, whereas they believe that strips for a Walgreens or CVS store branded monitor must be purchased at that particular retail outlet. Store brands also offer an additional marketing benefit for the retailer who can tout that they are helping customers save money.



HDI to sell their systems at a lower price point. Unlike LifeScan, Roche, Bayer or Abbott, HDI does not need an army of sales people nor do they need to spend millions to promote their brand.

Based on these factors, it should shock no one that the future of the BGM market is bleak. The market is already down the path of the personal computer market which converted from a technology based market to a commodity market. Just as the PC industry consolidated from a host of players into a mere handful, so will the BGM market. After the coming consolidation, the remaining players will

focus primarily on controlling costs and maximizing margins. Test strip usage will decrease as insulin using patients will become the primary customer base.

Ten years from today, Diabetic Investor predicts that when a patient looks for a monitor, they'll find fewer options at prices below where they stand today. Brand name products will face an uphill fight against value options. In the end, the industry will be a mere shell of what it once was.

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