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## DIABETIC INVESTOR



### “Make the Connection” David Kliff, Publisher

### AADE Recap

In the next few weeks, millions of children will be headed back to school. A quality education is one of the cornerstones of the American Dream. Over the years, politicians, teachers and parents have been involved in a hot debate over what tools students need to receive a quality education. Smaller class sizes, school vouchers and annual testing of teachers are just some of the ideas that have been discussed.

In many respects, this debate is not unlike what’s happening in the world of diabetes. While everyone acknowledges that patient education is critical to better outcomes, no one seems to know the best method to get patients the education they desperately need. This issue was crystallized at the American Association of Diabetes Educators (AADE) annual conference.

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As in past years, educators had several explanations for why patients fail to receive education. Poor reimbursement policies, as usual, was tops on the list. Ask almost any educator and they’ll be more than willing to tell you how they are overworked and underpaid. While Diabetic Investor generally agrees with this view, better reimbursement policies alone will not solve the education problem. This view also ignores a fact well known but rarely discussed, that achieving good control is hard work. Even well educated patients can have a difficult time keeping their diabetes under control.

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While it is quite obvious to anyone in the world of diabetes and to many outside the diabetes world, patients don’t live their lives in a vacuum where controlling their diabetes is their only concern. Patients with diabetes have regular lives just like everyone else except they have a disease that requires around the

clock attention. There are no days off; diabetes is a 24x7x365 battle.

This point was made clear during a presentation at the AADE on continuous glucose monitoring by Francine R. Kaufman, MD Professor of Pediatrics from the Keck School of Medicine at the University of Southern California. Dr. Kaufman gave a wonderful overview of how glucose monitoring has progressed over the years and the benefits of continuous monitoring. During the presentation, Dr. Kaufman showed a slide which summarized one of her studies that was published in Diabetes Care. The study involved 47 patients new to

CGM with a mean A1c of 8.61; after three months of using a CGM, mean A1c fell to 8.36; hardly a dramatic improvement and not even close to the American Diabetes Associations (ADA) A1c goal of 7 or less.

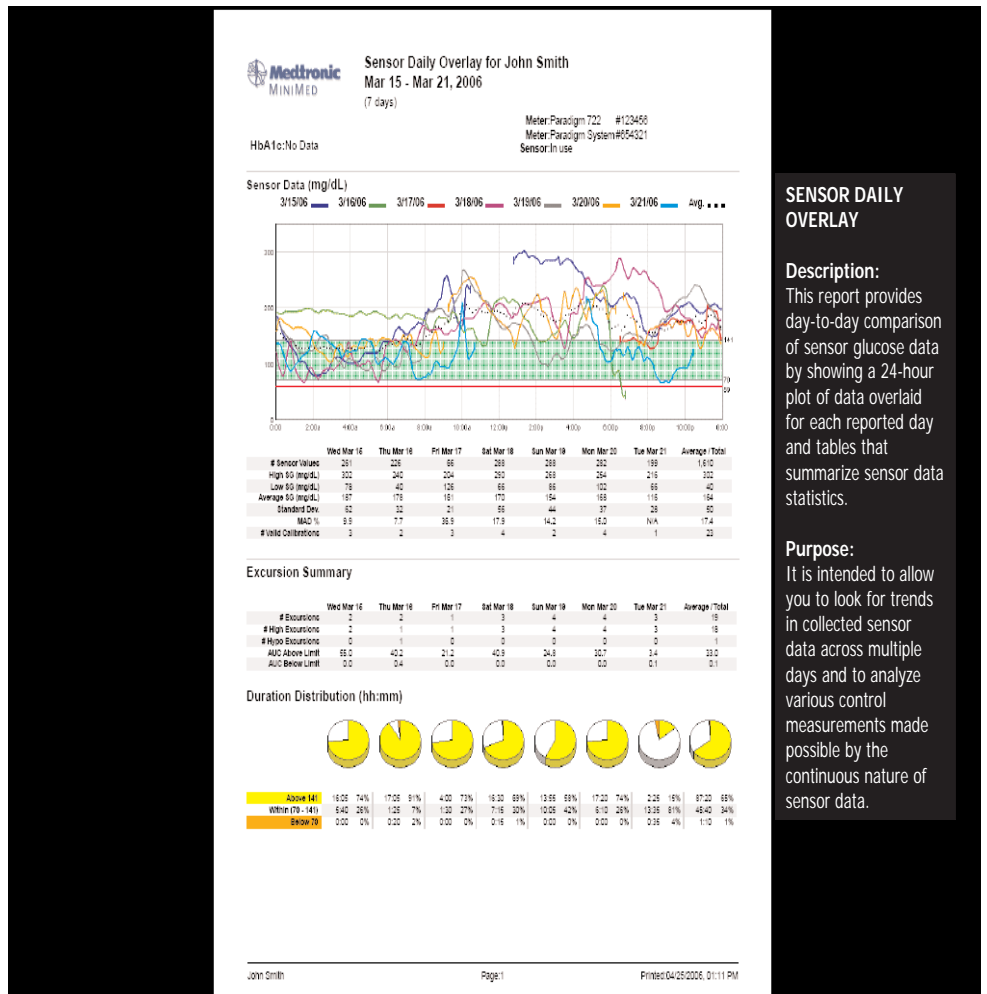
What truly struck Diabetic Investor was the amount of work Dr. Kaufman's patients had to go through. Besides having to learn how to use the CGM, patients were required to complete detailed logs. Yet, even with all this work, education, and the benefits of being in a controlled setting, the results were less than impressive. This is just one more piece of evidence that shows just how difficult it is to achieve good control.

While other studies involving CGM have shown better outcomes and Diabetic Investor does believe CGM can be a valuable tool, the fascination with CGM points to a bigger problem for educators, physicians and, most importantly, the patient. Thanks to advanced technology, patients with diabetes now have a host of tools available to help them manage their diabetes. Besides CGM, there are several "smart" insulin pumps, glucose meters have become mini-computers, there are hundreds of diabetes related web sites and blogs, not to mention all the new drugs. Yet, somewhere along the way, with all this advanced technology and new drugs, information has become confused with knowledge.

Looking over the current state of patient education, there are far too many information sources and far too few knowledge enablers. CGM is a perfect example of this. The current crop of CGM systems provides a patient with as many as 288 glucose

While researchers, physicians and patients generally acknowledge that CGM is a useful tool, the systems provide an enormous amount of data. Pictured below is just one of several reports available from Medtronic's CareLink® program. CareLink is a powerful tool that allows a patient to download data from their pump, CGM and log book.

Even with advanced software programs such as CareLink, someone must analyze the data. This is hidden issue with CGM, as valuable as this data is especially when combined with insulin and food intake, analyzing the data is a time consuming process. In a clinical setting when patients have the assistance of physicians and educators this isn't an issue. However, in the real world all this information can be overwhelming.



**SENSOR DAILY OVERLAY**

**Description:**  
This report provides day-to-day comparison of sensor glucose data by showing a 24-hour plot of data overlaid for each reported day and tables that summarize sensor data statistics.

**Purpose:**  
It is intended to allow you to look for trends in collected sensor data across multiple days and to analyze various control measurements made possible by the continuous nature of sensor data.

readings a day. This data has allowed patients to see their glucose levels in a different perspective. The CGM users interviewed by Diabetic Investor consistently state that the most valuable aspect of using a CGM is what they call, trend data. The CGM allows these patients to develop a data base which can then be combined with other information

which in turn allows them to more effectively manage their diabetes. It is this last point that's critical. First, these users understand that glucose readings by themselves do not tell the entire story. To these advanced users, using glucose readings alone to manage their diabetes is like asking someone to drive to a pre-

viously unknown destination without a complete set of directions. They understand that to achieve good control glucose readings must be combined with other information such as food intake and activity levels. Finally, and most importantly, these users know what to do with the information once they have it. This is the difference between information and knowledge. Knowledge is the ability to apply the information gathered into an action step.

To Diabetic Investor, this is the essence of patient education, helping patients gain knowledge so they can apply the information they gather into a positive action step.

It does no good to train a patient on how to use a glucose monitor if they don't know what to do with the test results.

Based on the products displayed on the AADE exhibit floor, it's quite clear that increasing patient knowledge has taken a back seat to gathering even more information. Some companies see the role of the educator and/or physician as being the knowledge enabler. With this approach, the patient merely gathers the information which is then transmitted to their educator or physician for analysis. An example of this approach is the Virtual Tracker Comprehensive Diabetes Management System from HMD BioMedical. According to company literature, "The Virtual Tracker is an on-line solution enabling Providers, Physicians and Healthcare Professionals to work together as a team in managing their patient's diabetes. Everyone is working towards one common goal, to lower the risk and onset of common modalities associated with diabetes."

The Virtual Tracker- Just one of several devices that downloads glucose readings to a central server. Conceptually this is not a bad idea; however, the economic realities of diabetes management could slow adoption. Simply put, after the data is downloaded is the physician or educator going to be compensated for their time analyzing the data and making recommendations.



Photo Courtesy of HMD BioMedical

The system combines a glucose meter that connects with a cradle. According to the company, the cradle downloads the stored readings and uploads them to their server. This data can then be accessed by the patient or anyone that has authorization, such as the patient's physician or educator. It is then up to the educator and/or physician to analyze the data and get back to the patient. Let's ignore, for the moment, that as pointed out earlier, glucose readings alone are only part of the picture and concentrate instead on the economic realities of this concept.

The economic reality of diabetes management centers on two impor-

tant factors, time and money. Will the physician and/or educator have the time to analyze all this data and, if they do, how will they be compensated for their time? Third party payers are already reluctant to pay for patient education; it's a wonder that so many companies believe they will pay for data analysis. HMD BioMedical isn't the only company that has this type of system; they are just one of several. Yet, for any of these products to be commercially successful, it requires a paradigm shift in reimbursement policies, which is something Diabetic Investor sees as unlikely anytime in the near future.

Taking a different approach to this never ending quest of helping patients gather information are the many blood glucose monitoring companies. As meter technology has progressed over the years, the BGM market is transforming into a market where market share, formulary placement and price are trumping technology. With the exception of an all in one device that combines a glucose meter and a lancing device into one unit, meter innovation has come about as far as it can go. Small blood samples, alternate site testing, enhanced memory and analytical software are now standard features throughout the industry.

As the results of the major BGM companies have shown, the market growth for BGM has slowed dramatically. In the past, double digit growth in the BGM market was the norm, today it's the exception. Even with the epidemic growth rate of the number of people with diabetes, market growth is anemic. This is in spite of the fact that all the major meter com-

panies have dramatically increased their marketing budgets. Besides having an army of sales representatives giving away free samples to educators and physicians, expensive television advertising is now a normal cost of doing business.

Simply put, for all the advancements in meter technology, huge marketing budgets and increase in the number of people with diabetes, the BGM market growth rate is below 10% annually. It seems that in a mature market, when growth stalls, gaining market share becomes the mantra for BGM companies. It was only a matter of time before a major player made the decision to initiate a price war. In this case, that player is Abbott (NYSE:ABT). After acquiring Therasense, the company instituted an aggressive pricing structure to gain share. Initially this strategy

This price war has created another problem for the major players: how to maintain their normally fat margins. So far, the strategy du jour is to develop one test strip that can be used in more than one meter. At the AADE, LifeScan introduced their Horizon meter, previously only available overseas, to the U.S. market. The meter will be called the UltraMini in the U.S. and use the same test strip as their OneTouch line of meters. Abbott is also following this approach as the FreeStyle test strip can be used in three different meters. Although Roche has not yet pursued this strategy of one test strip and multiple meter options, they are surely considering it.

Looking towards the future, the major players have to be concerned as there are a host of smaller companies more than eager to nibble away

The OneTouch UltraMini, LifeScan's entry into the value segment of blood glucose monitoring.



worked and Abbott gained share. It wasn't long before LifeScan, a unit of Johnson and Johnson (NYSE:JNJ) and Roche, the two market leaders, decided to fight back. This strategy has slowed Abbott and made the meter business even more competitive.

Photo Courtesy of LifeScan

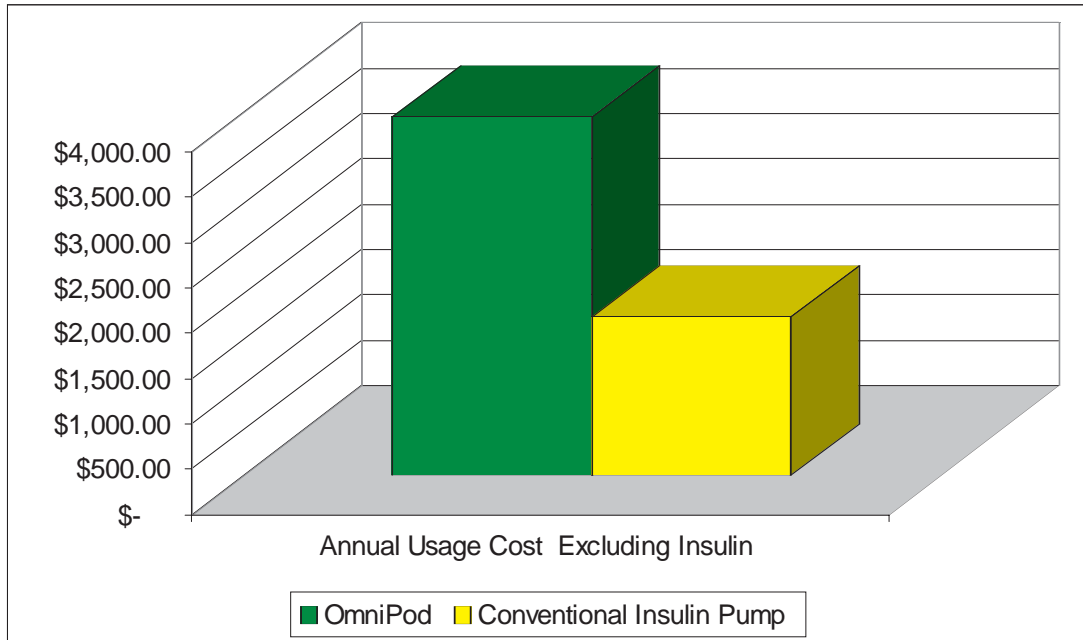
at the majors' market share. Not burdened with huge infrastructure costs, these players have a major cost advantage. Take privately held AgaMatrix and their deal with PolyMedica (NASDAQ:PLMD).

Although not yet facing pricing issues, another market having issues of their own is the insulin pump market. Medtronic (NYSE:MDT) is not only the market leader with nearly 70% of market share, they also own the majority of patents in the insulin pump arena. The company has already successfully used this patent portfolio to force Smiths, the owners of Deltec (the makers of the Cozmo insulin pump), into a settlement. Now that Animas, currently number two in terms of market share, is owned by JNJ, the company has become Medtronic's next target. Look for Medtronic to sue Animas/JNJ over the same patent issues they used to force Smiths into a settlement. With the OmniPod from Insulet gaining traction, don't be surprised if Medtronic has a plan in place once the company goes public or is acquired

AgaMatrix makes the meter for PolyMedica's Liberty Medical Unit, the largest provider of diabetes supplies to the Medicare market. With nearly a million customers, Liberty has the size and influence in a large and growing patient population. Liberty also has tremendous control over which meter their customers use. The government sets the price that Liberty can charge for meters and test strips; the less Liberty pays the more they make.

Liberty also knows that in the eyes of their customers, all meters do basically the same so it really doesn't matter which meter they use as long as it works. The AgaMatrix deal has given the company tremendous

What would happen to the insulin pump market if a conventional pump company moved towards a lease rather than buy pricing model? Currently the OmniPod from Insulet has a major cost advantage over conventional pumps when total cost (cost of the pump plus annual pump supply costs) is used as the comparator. Take away the large upfront cost of a conventional insulin pump and use annual usage costs as the measure the OmniPod systems loses its advantage.



leverage and basically puts them in a win-win situation. They know the majors will do almost anything for market share and therefore can be aggressive in their pricing demands. Even if their demands aren't met, they have the AgaMatrix meter which carries the respected Liberty name.

Patients with diabetes are already an expensive proposition for third party payers and the day is coming when these payers follow the Liberty strategy. Third party payers already exert influence over their patients, only now they use formulary placement as the weapon of choice. A patient may like the OneTouch Ultra better than the FreeStyle Flash, but brand loyalty goes out the window when they have to reach into their pocketbooks. Although there is a minority of patients who are willing to pay high-

er co-payments should their provider change preferred meter companies, the majority won't. Think about what would happen should providers follow the Liberty model and have their own co-branded meter.

There are some who believe this possibility is remote, claiming payers have no interest in being in the meter business. They're right. Payers don't want to be in the meter business. They're in business to make a profit and profits in healthcare come from controlling or limiting costs. It's not difficult to see the day when payers contract with PolyMedica to handle their patients with diabetes. If not PolyMedica or one of their competitors, there are a host of disease management companies and pharmacy benefit managers more than willing to step in. There was a time when people thought mail order delivery of

drugs was a pipe dream. Today it's the fastest growing segment. Meters and test strips easily fit this model because there is little need for pharmacist interaction.

Cost has become the dominant factor here. The majors have already adopted cheaper manufacturing opportunities overseas. The next step in cost control is eliminating infrastructure costs. The people who run the meter business at the majors have to answer to their bosses, who in turn must answer to the Street. The Street rewards growth and earnings consistency. Given the dynamics of the BGM market it's only a matter of time before the majors will be faced with some very unpleasant options. Margins are already under pressure and the trend is not promising. These companies have huge investments in their brands and while margins may

not be what they're used to, they're still hefty. Faced with the choice of exiting the business or cutting costs, cutting costs will be the winner.

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In many respects, the OmniPod actually poses a greater threat to Medtronic than Animas. Medtronic has a clear technological edge over Animas while the OmniPod is truly innovative technology. More worrisome to Medtronic is OmniPod's pricing structure. Unlike conventional pumps which cost \$6,000 or more just for the pump, the OmniPod starter kit is priced at \$800. As we pointed out on these pages before, on a total cost basis, initial pump cost

plus annual pump supply costs, the OmniPod has a major advantage. It's not until year three of usage that OmniPod reaches total cost parity with conventional pumps.

Even with their unique technology and unique pricing structure, Insulet knows they must lower their annual usage cost. Take away the initial cost of the pump and conventional pump usage costs are about \$1,700 a year compared to nearly \$4,000 for a year's worth of Pods. Should Insulet bring annual Pod costs in line with current pump disposable costs, Medtronic could have a real problem on their hands. Even without the OmniPod, Medtronic may be facing this situation as other pump companies are considering a move towards a version of a BGM market business model.

Instead of giving the pump away for free to generate continuing revenue from the sale of disposables, the pump market could move to lease rather than buy model. Under this pricing model, the patient has an annual lease payment which covers the pump's manufacturing costs and continues to purchase pump disposables. This is not unlike the automobile market where leasing has exploded. Why spend \$40,000 or more when for a few hundred dollars a month a consumer has almost all the same benefits as someone who purchases the car outright. At the end of the lease, the consumer simply returns the car and the process begins all over.

The insulin pump market actually is better suited to the leasing option as under this pricing model patients would have the opportunity to consistently upgrade as pump technology improves. This model would also be embraced by third party payers who would no longer have to spend thousands each time a patient begins pump therapy or replaces an out of warranty pump. The insulin pump market is already over-crowded and dominated by one player. Should the competitors to Medtronic and Insulet continue to do business as usual, the insulin pump market could soon be limited to just two options.

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