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**Medical Technology:** Industry Update

## **Results From Our CGM User Survey and Our Thoughts on Insurance Coverage**

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### **INVESTMENT HIGHLIGHTS**

Two FDA-approved continuous glucose monitoring (CGM) systems were introduced to the diabetes glucose testing market in mid-2006 as an adjunctive technology to fingerstick blood glucose testing. We surveyed 57 diabetic patients for their experiences in selecting and using CGM devices.

#### **Some key findings from our survey:**

- We found that patients are using sensors for much longer than labeling claims stipulate. In the absence of broad insurance coverage, we expect patients to keep using all sensors longer than labeling claims stipulate.
- We had assumed that brand loyalty, especially among pump users, would present a competitive advantage to Medtronic and we think our data supports this. However, while brand loyalty does play a role, our data also shows that product performance is the most important factor. Based on our data, performance satisfaction is similar for both devices.
- DexCom users were more price-sensitive than Medtronic users. In the current limited-reimbursement environment, we think that DexCom's recent price increase to coincide with the SEVEN launch could alienate some customers unless better performance is demonstrated.
- After trying a device, 19% of patients partially or completely abandoned the technology. Of these users, 64% cited cost as a reason, and 82% cited performance issues. Although both Medtronic and DexCom have recently made progress with regard to the performance of their most recent offerings, we think both concerns will persist in the near term.
- Only 8 of 57 respondents have managed to obtain insurance reimbursement from a private payor. We continue to think that insurance coverage will be key to driving revenues, and we expect that the technology will be largely limited to early technology adopters until broad reimbursement is in place.

#### **Our thoughts on reimbursement:**

- Given the cost of the durable devices, the additional cost of the sensors, and the fact that the technology is adjunctive to fingerstick glucose measurement, we think private payors are going to require strong data before providing broad reimbursement coverage.
- We think the JDRF CGM study is a step in the right direction. However, we also note that recent data presented at the ADA by Dr. Irl Hirsch shows that patient adherence should not be taken for granted although it is likely critical to demonstrating efficacy.
- Based on the feedback from our user survey, in which some patients reported discomfort and other frustrations, we think that intensive patient management by JDRF trial physicians may be critical to collecting convincing data. We expect broad reimbursement to start in 2009.

## INTRODUCTION: CGM SYSTEMS

Two FDA-approved continuous glucose monitoring (CGM) systems were introduced to the diabetes glucose testing market in mid-2006 as an adjunctive technology to fingerstick blood glucose testing. Recall that CGM devices consist of a sensor that is inserted under the skin to read interstitial fluid glucose levels and a separate durable component that displays the data received from the sensor. We think that the continuous glucose trend data collected by using these devices has the potential to add another layer of understanding to diabetes disease management, but the lack of insurance coverage as well as patient usage and performance challenges have, in our opinion, impeded large-scale adoption so far.

*Two CGM devices currently are approved, and a third device may soon enter the market.* The two CGM devices currently on the US market are Medtronic's Guardian Real-Time (RT) and DexCom's STS. Note that DexCom began the launch of its SEVEN STS CGM system, which has a 7-day usage approval, in late June 2007. We believe that our survey data reflects usage of DexCom's 3-day sensor product, which is now gradually being phased out. Note also that Abbott's Navigator has recently received CE approval and is currently being used in some US-based trials, including, we believe, a trial by the Juvenile Diabetes Research Foundation International (JDRF). The JDRF trial is expected to provide data that will be supportive of insurance reimbursement efforts for the products. Data from the trial is expected near the end of 2008. Abbott has stated that it expects US approval for the Navigator by the end of 2007. We note, however, that Abbott's approval estimate for this product has been pushed back several times. The Navigator received a CE mark in June 2007, which we think increases the likelihood of, but by no means guarantees, US approval.

## CGM USER SURVEY RESULTS

For our CGM user survey, we polled 57 diabetic patients who had experience with CGM systems. The users answered 17 multiple-choice questions in our web-based survey and also had an opportunity to add comments as appropriate.

### Key Findings About CGM Users

*More than half of the respondents have had diabetes for more than 10 years and most are, in our opinion, aggressively self-informed and well-educated disease-managers.*

For reference, we note that 9 of the 57 patients surveyed were Type II diabetics and the remaining 48 patients were Type I. Of the patients surveyed, 54% were diagnosed 10 or more years ago, 16% were diagnosed 5-10 years ago, 11% were diagnosed 2-5 years ago, and 19% were diagnosed within the last two years.

Sixty-one percent of patients said that their disease is primarily managed by an endocrinologist. Notably, 11% of patients said that they manage their disease primarily on their own, with some help from an endocrinologist or primary care physician.

Also of note, 68% of respondents said that their primary source of information was the Internet or blogs, versus the 26% who said that their medical professional was their primary source of information. *We had expected that users of CGM devices would be informed, hands-on, early technology adopters, and we think that these statistics reinforce our theory.* While we acknowledge that our web-based poll was likely to target tech-savvy, self-informed patients, since CGM devices have been available for only about one year and with very limited reimbursement, we view this well-motivated group of patients as the key user group.

Most of the 57 respondents (63%) have been using a CGM device for less than one year, which we expected as the products were only recently approved. Recall that DexCom's STS was approved in June 2006 and Medtronic's Guardian RT was approved in July 2006. Three of the 57 users reported using their CGM device for longer than two years, including two users who participated in clinical trials for Abbott's Navigator, which is not yet approved in the US.

### How Patients Use CGM Systems

*We found that patients are using sensors for much longer than labeling claims stipulate.*

Overall, the average patient uses a sensor for 5.5 days, despite the fact that labeling claims for both products are for 3 days. (We note that DexCom's new SEVEN is for 7 days, but that product is still undergoing an initial roll-out to patients.) Patients reported using the 3-day labeled sensors for up to an average of 7.4 days (responses ranged from 2 to 24 days) when

asked for their longest-wear period. We think that especially in the absence of broad insurance reimbursement, patients will continue to use the sensors longer than labeling claims stipulate, rather than adhering to labeling claims. Based on anecdotal evidence, we believe many patients are using the sensors until failure (i.e., the device readings become obviously inaccurate) and we think that recent adopters will tend to wear sensors longer once they are more familiar with their device.

Based on other conversations with patients, we think the SEVEN is enjoying mixed reviews, much like DexCom's 3-day STS and Medtronic's Guardian RT, and is also being used for longer than labeling claims stipulate. We think patients are resetting the devices after day seven and wearing the sensors until failure. We have heard favorable comments that the SEVEN offers some improvements over the 3-day STS, i.e., its smaller insertion needle and water-resistance, but we also have heard of user interface issues with the device software, a complaint noted about all products so far. We note that about one quarter of patients surveyed rate software performance as a key factor in choosing a device.

**The bottom line.** In the absence of broad insurance coverage, we expect that patients will continue to use all sensors longer than labeling claims stipulate. Due to the sensitive nature of the technology, as well as the risk of alienating customers who are largely paying out of pocket for the technology, we think it is unlikely that either company would incorporate an absolute cut-off feature. Therefore, we believe sensor sales will not ramp to their expected potential based on labeling claims until coverage is in place.

## Medtronic's Guardian RT Versus DexCom's STS

### *Selection Process*

We asked the patients to identify their top three reasons for selecting a product. Among those who used the Guardian RT, 64% listed product performance, 50% listed brand loyalty, and 35% listed physician suggestion. Among users of the DexCom STS, 63% listed price, 59% listed performance, and 46% listed physician suggestion.

We think these results underscore several ideas. First, product performance, especially of devices such as these that are sold to a highly informed early-adopter patient group, is a key factor. Second, *Medtronic, with its strong insulin pump franchise, has an advantage among brand-loyal consumers and consumers who want to interact with only a single sales representative and/or support staff for their diabetes needs.* Third, less than half of both user groups listed physician suggestion as a top reason for selecting a device, which again implies that users are quite self-informed.

Roughly one quarter of respondents (25% Guardian and 23% DexCom) specified software performance as a top-three factor in their decision. *We think this speaks to the sophistication of these relatively tech-savvy early users since they care to download data and look at trends and other metrics.* Based on recent conversations with users, we also believe that software performance is lacking in all product offerings, including both the Guardian RT and DexCom's 3- and 7-day products. We therefore expect both companies to continue offering next-generation products and upgrades that may result in an increased cost burden on the patient if the durable portion of a product has to be replaced. However, we also think this will eventually result in better performance and more acceptance of the products.

*Our survey data implies that DexCom's customers are the most price-sensitive.* Previously DexCom's 3-day STS sold for \$400 per durable plus \$35 per sensor. The SEVEN sells for \$800 per durable plus \$60 per sensor. (Note that a \$150 durable upgrade is available for existing DexCom customers.) The Guardian RT costs about \$1,000 for the durable portion and \$35 for a 3-day sensor. So, DexCom's SEVEN sells for close to the same price as Medtronic's Guardian RT. Despite the product labeling, we think that, based on our conversations with patients, the SEVEN sensors are used for the same number of days as the 3-day sensors, so in many cases patients are paying more per sensor than they were when using the 3-day STS.

**The bottom line.** As we expected, DexCom users were more price-sensitive than Medtronic users. Although we think this will be somewhat of a moot point if and when insurance reimbursement comes about, in the meantime we think that DexCom's recent price increase to coincide with the SEVEN launch could alienate some customers unless better performance is obvious to them. It has often been assumed that brand loyalty, especially with pump users,

would present a competitive advantage to Medtronic and we think our data supports this idea. *However, while loyalty does play a role, our data shows that product performance is the most important factor.*

### **Satisfaction**

Of the 22 users who had tried DexCom's device, 41% were very satisfied, 41% were satisfied but would be willing to try another device, and 18% were not satisfied and were using the device only intermittently. Of the 28 Medtronic users, 39% were very satisfied, 50% were satisfied but would be willing to try another device, and 11% were not satisfied and using the device intermittently. Interestingly, in both user groups, no respondents were completely unsatisfied to the point that they were longer using a device at all.

Patients' initial impressions of Abbott's Navigator appear to be positive. When asked if they would consider Abbott's Navigator if it is FDA approved, 47 of 57 respondents said they would. When more details were provided, several patients said they thought that the Navigator might be more accurate. Four of the Medtronic customers said they would not consider using the Navigator because they want their pump to be the same brand as their CGM device. The remaining CGM device users who said they would not consider Abbott's product cited expense/reimbursement as the primary reason. Several patients also said they would be concerned about start-up failures and long warm-up times in using the Navigator, although those patients were still interested in trying out the device. Since the device has not yet been approved, we cannot speculate on these concerns, but we do note that expectations regarding the device's performance are quite high.

**The bottom line.** In our view, patients are largely open to trying the different products and are looking for the best-performing device. However, until reimbursement is in place, we do not expect patients to switch devices often owing to the high start-up costs (approximately \$1,000 for the durable). We also note that, based on our data, expectations for Abbot's not-yet-approved Navigator seem quite high, although we think this is largely speculative. We believe the optimistic expectations for the Navigator could be due in part to users discussing the challenges and learning curves they have experienced with the two approved products while having only limited data regarding the Navigator. We do note, however, that all three of the patients involved with the Navigator trials said they were very satisfied.

We think that both DexCom's and Medtronic's products are works-in-progress to some degree and we expect new versions of the products to continue being rolled out over time in response to market demands. DexCom's SEVEN sensor is designed have the smallest insertion needle and is water-resistant; we think these attributes demonstrate that DexCom is working to respond to patients' demands. Also, DexCom has previously mentioned that it is working on a next-generation product to follow the SEVEN. We think Medtronic, too, has responded to patients' needs by developing a smaller sensor, as well as pediatric models of their most recent product versions. Medtronic released the new version of the Guardian RT in March 2007, along with a pediatric offering. We expect that both DexCom and Medtronic will continue fine-tuning their devices in next-generation products.

### **Why Patients Stop Using the Devices**

The 11 patients who started and completely stopped using the devices cited expense and dissatisfaction with performance as reasons. Five of these patients mentioned cost or lack of insurance coverage as a reason. Nine users were dissatisfied with the performance and complained that the products were "bulky," "not waterproof," and/or "painful," and that sensors were "inaccurate" and "faulty." (Note that some users cited both cost and performance/pain issues as reasons.)

Two additional users said that while they have not completely abandoned the technology, they have cut back on usage and take "breaks" in order to make the system more affordable.

**The bottom line.** Sixty-four percent of patients who either abandoned the technology or substantially reduced usage cited cost as a reason, and 82% cited performance issues. Although both companies have recently made progress with regard to performance attributes of their most recent offerings, we think these concerns will persist in the near term. In our view, broad reimbursement (which we expect in 2009) and more reliable or easier-to-use next-generation products will be key to attracting and retaining more users.

## Reimbursement Findings

We believe that seeking insurance reimbursement is a long and often fruitless process at this point. Users of both DexCom's and Medtronic's offerings have had only limited success in attaining reimbursement. We estimate that a total of about 24 of the patients we polled have had lengthy interactions with their insurance companies, with 8 receiving some reimbursement, 8 being denied outright, and 8 still in negotiations. The remaining respondents said either that the devices were not covered or that they did not have any insurance. Three DexCom users reported reimbursement ranging from 50-90% of costs. Five of the 28 Medtronic users successfully obtained insurance coverage and received 70-100% of costs. For both devices these decisions appear to be made on a case-by-case basis and getting insurance coverage is clearly an uphill fight at this time.

When asked what effect broad insurance coverage would have on their CGM device usage, 46% of all 57 respondents said that they would use their devices more often. Another 19% said they would start or re-start using devices. A third of users said there would be no change in their usage, which we believe implies that these users are paying the total amount out-of-pocket and using the products constantly. Only 2% (1 individual) of respondents said they would not use a CGM device at all, even with insurance coverage.

## OUR THOUGHTS ON REIMBURSEMENT

We think private payors are going to require efficacy data before covering CGM systems because the devices are costly and adjunctive to fingerstick testing. We believe that an important potential source of such data may be the randomized controlled trial sponsored by the JDRF, and we expect full data from this trial to be available in early 2009.

The JDRF began enrolling its randomized controlled trial to support approval of CGM devices in December 2006. The trial is designed to enroll 450 patients at 10 sites, and the patients are randomized into two groups: CGM users and fingerstick (control). For the first six months, the patients are to be closely monitored by physicians. At the end of the first six months, the primary endpoints of HbA1c levels, episodes of hypoglycemia, and blood glucose levels will be measured. The second six months of the trial will involve less intensive patient management to observe the effect on the same endpoints. The trial is designed to see if any benefits observed in the first six months are maintained when the patient is less intensely managed by a physician. We think that data from this trial will be important as private payors decide whether or not to cover CGM devices.

Notably, a study by Dr. Irl Hirsch of the University of Washington Diabetes Center was presented at the American Diabetes Association (ADA) meeting in June and was referenced in a *JAMA* article earlier this month (*JAMA* 298, no. 6). Dr. Hirsch and his colleagues studied 138 experienced pump wearers in a 6-month randomized multicenter trial, randomized to using a CGM or fingerstick. Dr. Hirsch's data suggests that patient adherence is key to seeing therapeutic benefit from the devices and that poor adherence resulted in poor results. Specifically, users who had less than 60% adherence saw no benefit. (100% adherence was defined as using the sensor for six days per week.) Interestingly, Dr. Hirsch stated that "These people with the higher HbA1c levels were not taking care of their diabetes before the trial and if they're not interested and focused, this won't help them."

**The bottom line.** Given the cost of the durable devices (approximately \$1,000, replaced about every six months), the additional cost of the sensors (more than \$3,000 per year), and the fact that the technology is adjunctive to fingerstick glucose measurement, we think that private payors are going to require strong data before they provide broad reimbursement coverage. We believe the JDRF study is a step in the right direction, but we also note that recent data presented at the ADA shows that patient adherence should not be taken for granted although it is likely necessary to proving efficacy. Based on the feedback from our user survey, in which some patients reported discomfort and other frustrations, we think that intensive patient management by JDRF trial physicians may be critical to collecting convincing data.

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Abbott Laboratories (ABT, \$52.52, Not Rated)

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