

DIABETES CLOSE UP

Diabetes Close Up, V3, #7
March 23, 2004

National Diabetes Alert Day/Medtronic Musings

The short version

1. **Happy National Diabetes Alert Day!** It doesn't have the same ring as Happy St. Patrick's Day, does it? BUT what an excellent writer's briefing the ADA put on earlier today in New York! Dr. James Gavin, always an outstanding speaker, gave an excellent, very targeted presentation on the link between diabetes and cardiovascular disease – see our “longer version” below for the highlights of his and other discussions.
2. **Medtronic update:** MDT gave its mid-quarter update last week. Our reading of diabetes health was mixed. That said, no doubt MDT continues to be a beneficiary of Disetronic's absence from the US market.
 - Reading between the lines, it appears that although pump sales sounded relatively strong for the quarter, MiniMed's current quarter will be a bit weaker than expected due to some Quick Set Plus issues. One positive – Medtronic has an extra week in its quarter this time – they said diabetes will benefit “less than procedure businesses” from this – no doubt the disposables issue will be a drag that will offset the extra week, but still, the extra week comes at a good time.
 - The company referenced a "supply issue" in its comments related to disposables and said this might slow growth in C4Q.
 - In the Q&A, management noted that there have been quality concerns with Quick Set Plus that are “working through the system” and that they have been trying to build supply back up of Quick Sets.
 - Management said it believed this would be resolved in a month or two, which is good news for patients on MiniMed pumps – there is little that strikes as much fear in a patient's head as the thought that their supplies are low. Since it would probably be pretty tough to fix problems in such a short time, we imagine Medtronic will stop manufacturing the Plus (likely already have) and go back to the Quick Set, which was manufactured by Maersk.
 - Of course, the profit margins must have been better for Medtronic with the new Quick Set Plus, but sounds like it could've been launched a bit too early; user complaints on the chat boards show various problems, many related to insertion (but not necessarily readily detectable at insertion). The next question is how long it'll take to get a new version of the “Plus” – it sounds like design has caused headaches from the start.
 - On its site, Medtronic shows "tips" for using Quick Set Plus that may help users who have had problems. Also offered is a \$299 upgrade offer for 511.
 - For its diabetes/neuro franchise, C4Q will be slightly better than C3Q; Medtronic expects sequential and full year growth.
 - Notably, new alarm product Guardian will have a "full launch" at ADA – this implies an initial launch at some other point. This corroborates what we've been hearing in response to our frequent questions on this front – various versions of “not likely before summer.” This will be a very interesting product to watch – although we doubt it'll be reimbursed (no substitute label), it'll be fascinating to see how well it works, how many errors there are, how patients use it. Although it'll give high and low alarms only, and no real-time data, we actually believe this might be a positive “half-way” step – at least they don't have to worry yet about how consumers will interpret all the data (though this will be a concern if alarms have errors – but in this case, when alarmed, users will need to check with a traditional monitor, so we imagine little liability).

The longer version

Appendix A: Happy National Diabetes Alert Day! ~ More on Medtronic

1. **Writer's Briefing:** The 1st ADA/NDEP Writer's Briefing, "A Report on the State of Diabetes and Cardiovascular Disease" was held in New York on March 23rd, 2004 - Diabetes Action Alert Day - and drew approximately 20 members of the press. Overall, an excellent slew of speakers stressed the importance of empowering the patient with knowledge of risks, complications, and the keys to good self-care, and emphasized the media's ability to impart the information to raise public awareness. They want more media! And no doubt, they should receive it – we need to do everything possible that's cost-effective to lower the burden of this huge public health liability. Significant points stressed:
 - **Spreading awareness about the risks of diabetes represents a major challenge.**
 - A "Make the Link" survey showed that > 2/3 of people with diabetes do not consider cardiovascular disease (CVD) to be a serious complication of living with diabetes. 60% did not feel at risk for high blood pressure or cholesterol. That's out of flipping control in our view. That said, more type 2 patients do appear to have their cholesterol under control than their glucose – due in large part, we think, to the emergence (and great evidence and data) of statins. We're still waiting for diabetes' magic bullet ...
 - Dr. Nathaniel Clark, moderator and lecturer, noted that a significant gap exists between the facts and the perceptions among people with diabetes.
 - ABC's and aggressive therapy can prevent the risk of CVD. The "Make the Link" partnership between the ADA and American College of Cardiology urges education of "ABC's": A1C <7%, BP < 130/80 mmHg and Cholesterol- LDL < 100mg/dl.
 - Dr. Clark spoke about the oft-quoted increased costs of diabetes care, which has increased from \$98 billion in 1997 to \$132 billion in 2002. All of you know that, we know! A less well-known fact is that cardiovascular risks are the most costly portion at \$17 billion – that's nearly 20% of the \$92 billion in direct costs. Such cost estimates appear conservative because they don't account for the undiagnosed.
 - Patients with diabetes have a 2-4x greater likelihood of a heart attack, with an earlier average onset age and greater death rate.
 - 2/3 of patients with DM die of heart disease or stroke.
 - Citing the UKPDS study and the EDIC study, Dr. Clark said that aggressive glucose control, combined with blood pressure and cholesterol control, reduces risk of CVD in people with diabetes. He cited a 1999-2000 NHANES survey, published earlier this year in JAMA, which illustrated gaps between current and desired care:
 - Just 37% of type 2 patients had A1C < 7%, 36% had BP < 130/80, 48% had total cholesterol levels < 200.
 - Depressingly, only 7.3% were at goal for all ABCs.
 - Please go out and asked whomever YOU know with diabetes if they know their ABCs ... truly, we have to start at home : >.
 - **Cooperation with physicians is the key to meeting goals of good control with reduced complications** - powerhouse NDEP chief Dr. James Gavin said that patients can only achieve the ABC goals by working with health providers. We concur, and are troubled by poor reimbursement for doctors and CDEs, which we think will continue to prompt valuable HCPs to leave the field. So check out the fabulous site - www.ndep.nih.gov/diabetes/control/control.htm.
 - Gavin said that the keys to successful self-care management are 1) weight management; 2) healthy eating; 3) increased physical activity; and 4) drug therapy. While yes, these sound pretty obvious, they need to be made more explicit. WAY WAY WAY too many type 2 patients are "managing" their diabetes with "diet and exercise." Many of these patients should be on oral drugs or better yet, on insulin (the most cost-effective medicine around in our view and the key to longer lives).
 - With health providers (for those that have insurance – a real problem for many with diabetes), patients can find out target numbers, set goals, and figure out a good self-management program. Gavin included setting goals for weight loss, including increased

activity, smaller portions, less salt, less fat, high fiber, quitting smoking, taking aspirin, and greater compliance in taking medication.

- Gavin emphasized how critical it is to close the gaps between knowledge, actions, and outcomes through aggressive therapy and controlling ABCs.
- He also mentioned the fact that doctors have less and less time to visit with and get to know patients (to say nothing of covering every co-morbidity in a fifteen minute appointment), which makes the task of reducing diabetes complications even more challenging. Sigh – we have a very long way to go.
- **Women represent a main target of education because more women than men die of heart disease and women with diabetes face a 5x risk increase of CVD**, compared to men with diabetes, who face only 2x risk increase.
 - Cardiologist C. Noel Bairey Merz said that it is more important to be fit than to be lean. In fact, 1/3 of people with pre-diabetes can be classified as lean. She cited inactivity as one of the most important risk factors and referred us to www.womensheartadvantage.org for a risk assessment calculator. “*Heart failure is very preventable- we can literally see it coming.*”
 - She also noted that women with diabetes have decreased estrogen, which may attribute to their increased risk for CVD.
 - The ability to treat and reverse heart disease is very possible and she recommended five habits stemming from a study at the Harvard School of Public Health. Women who follow these tips have < 10% chance of getting heart disease:
 - Daily exercise “movement of the body through space”
 - Eat “Heart Healthy”
 - Don’t be > 25% of ideal bodyweight
 - Have one serving of alcohol a day (her expressed favorite)
 - No smoking
 - In closing: “*Targeting women is key in facing the serious risks of heart disease in diabetes.*”

--by Pamela Stuart Jones and Kelly Close

2. More on Medtronic:

- **What’s the issue?**
 - So it seems the main issues relate to insertion and adhesive, which result in the catheter coming out by mistake – and the user not knowing. Remember that pumps use only short-acting insulin – so even if someone goes just an hour with the catheter out and they’re unaware of it, it’s an issue. Even if it’s a user error, this is one that really scares patients¹, because the risk of DKA is so high.
 - Some users are also irritated because they didn’t realize they were getting new sets, they just started receiving them one day after they’d ordered the Quick Sets. So, we’ll see what happens – from what I understand, MiniMed is now having trouble sourcing a lot of Quick Sets so they are sending just one box every three weeks. Technically, this is all pumpers need, but it’s a bit scary to some to run so low on sets.
 - What’s actually happening to supply and what are the commercial implications? Management said they usually ship patients a 3-4 month supply and are now shipping 1-2 month supply; the site actually states they are shipping one box at a time, every three weeks, which obviously isn’t a plus for the cost structure – the margins will be lower and the average revenue per order for at least this segment of the quarter will be a third to half what it usually is. Plus, no doubt, they’ll have to send more free samples, etc.
 - All of this reinforces, of course, the utter importance of testing new products every which way possible – the downfall can be painful:

¹ I wear an Animas pump as some of you know – I switched around the time of Medtronic’s purchase of MiniMed. I had long loved MiniMed, but there were service issues at that time and I was impressed with the Animas innovation (smaller basal rate) and customer service. Only once in seven years has my catheter come out by mistake – Thanksgiving Day, 1998, just after I got the MiniMed 508C. I hadn’t properly checked the catheter was in my abdomen correctly (if you ever want to see something painful, come watch me put one of these in) and only when I felt awful and my blood glucose was 450 did I check the set to find that indeed, I had screwed up. This never happened again, but was very scary, because my blood glucose went from 100 to 450 in just a few hours – being without insulin can change one’s blood glucose *that* quickly. - KC

- Needless to say, the negative goodwill from pump users stemming from this issue isn't a positive for Medtronic.
- To boot, some healthcare professionals also view this pretty negatively as well. This is a time-consuming problem they cannot fix – they are dealing with hyperglycemia from many patients, including those such as pregnant women who watch their scores like hawks, and other hyper-intensively managed patients (8x testing or more per day).
- It occurs to us that reps are probably also very upset – they don't have any good answers on this front for patients and have no control over the issue.
- Here's hoping that Medtronic get the issue fixed quickly, and go back to the Quick Set. We're confident this will happen but will be updating readers if problems persist.
- Note that Children with Diabetes has a good summary on its website.
http://www.childrenwithdiabetes.com/d_0j_21k.htm

-- By Kelly Close

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