

DIABETES CLOSE UP

Diabetes Close Up, V2, #25
November 12, 2003

1. **Media Preview: Diabetes growth continues to explode:** Come Friday, we'll see the official report that 18.2 million patients with diabetes in the US at the end of 2002, up from 17 million in 2000. Thankfully, diagnoses rose.
 2. **Media Report:**
 - a. **Go USA Today** for prompting some real discourse on diabetes in honor of World Diabetes Day, November 14. Of note, **Dr. James Gavin says it is likely that inhaled insulin will come to the market in the next couple of years or so.** To boot, Frank Vinicor, director of diabetes programs for the CDC, talks about his views on the insulin pump, noninvasive testing, and possible timeline for a cure.
 - b. **Is obesity a disease?** Or isn't it? Debates rage. Special thanks to obesity expert Carrie Portis for highlighting this key *Washington Post* piece.
 - c. **New campaign strives for A1C<7 by 2007.** This could benefit the entire industry - insulin manufacturers to start – we'll be watching execution.
 3. **MDT F2Q03 results: Diabetes revenue rose 18%** to \$140 million and increased 13% sequentially. **In the immortal words of CFO Bob Ryan,** while it might be “a bit” premature to call complete recovery of the diabetes business, the market acceptance of the Paradigm 512 and Paradigm Link, which have now been available for full quarter, have been strong. No diabetes Q&A.
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1. **Media Preview:**
 - a. **Diabetes growth continues to explode:**
 - i. **Come Friday, we'll see the official report that 18.2million patients with diabetes in the US, up from 17million a year ago.** From 15.9 million in 1998 to 17.0 million in 2000 to 18.2 million in 2002, the latest date for which stats are available. *Although new cases have risen to 1.3 million in 2002 from 1.0 million in 2000, we're making headway on the diagnostic front – it's estimated that 5.2 million of current patients with diabetes are diagnosed – or 29% of the total, down from 5.9 million or 35% of the total in 2000.*
 - ii. **All the players should benefit from this,** from more aggressive treatment trends, as well as from new guidelines lower the acceptable level of blood glucose, to 100 mg/dL from 110 mg/dL for pre-diabetes. (see DCU V2, #24).
2. **Media Report:**
 - a. **Go USA Today** for prompting some real discourse on diabetes in honor of World Diabetes Day, November 14.
 - iii. While it's not typically on my daily reading list, *USA Today* had some innovative diabetes chats with respected healthcare providers. If interested, click on <http://cgi1.usatoday.com/mchat/20031112011/tscript.htm> or see the Appendix 1.
 - iv. Of note, **Dr. James Gavin says it is likely that inhaled insulin will come to the market in the next couple of years or so.** To boot, Frank Vinicor, director of diabetes programs for the CDC, talks about his views on the insulin pump, noninvasive testing, and possible timeline for a cure.
 - b. **Is obesity a disease?** Or isn't it? Debates rage. If it is deemed a disease, “*classification could hasten the approval of new medications and boost coverage for millions of people for treatment of weight-related problems,*” says the *Washington Post* – details in Appendix 2.
 - c. **New campaign strives for A1C<7 by 2007.**

- i. **A public service campaign backed by Aventis** urges patients with diabetes to reduce their A1Cs below 7.0. Although many feel it should be 6.5 (Canada urges 6.0 if patients can achieve safety), the fact remains that even to get to 7.0 we have a long way to go.
- ii. **The blueprint is a plan of action written by leading experts (representing key public health and medical organizations and led by the chairman of the NDEP - National Diabetes Education Project)** and urges 1) raising awareness of blood glucose control among patients with diabetes; 2) initiating treatment earlier and treating diabetes more aggressively as it progresses; 3) expanding professional education; and 4) improving the patient care structure.
- iii. **A survey was conducted in October with 500 American adults with type 2 diabetes** – while this isn't a very large scientific survey, still of note - nearly half didn't have any idea of what a good score is. See Appendix 3 for other findings.

3. **MDT F2Q03 results**

- a. **Diabetes revenue rose 18%** to \$140million and increased 13% sequentially.
- b. **In the immortal words of Bob Ryan**, MDT CFO, while it might be “a bit” premature to call complete recovery of the diabetes business, the market has enthusiastically accepted the Paradigm 512 and Paradigm link, which have now been available for full quarter.
- c. **The Paradigm 712 with a larger reservoir** was released at start of the current (FQ3) quarter. This is good – there were a lot of upset patients on this front, from what I understand. (Originally, it has been thought a higher concentration of insulin would be available, which would've made the smaller reservoir all right.) A new disposable set will also be introduced within the same timing.
- d. **MDT made a point of saying several times** it expects positive diabetes trends to continue.
- e. **Check out Art's remarks:**
 - i. **Medtronic will release a new pump at least every 12 months.**
 - ii. **The underpenetration of the pump market plus continuous advent** should allow diabetes to grow 20% in future – I agree that the impact of continuous will be major.
 - iii. **The question of the day for me with Medtronic has been when the Guardian (patient alarm continuous meter) will be released.**
 - 1. The company had said this year for some time – today's words were “over the next few months.” My guess is the launch may not hit calendar year as had been implied but probably will hit fiscal year.
 - 2. At the CDA, the Guardian was shown, and it was said to be approved in the US.
 - 3. At the DT meeting, a few weeks later, it was deemed *not* yet approved.
 - 4. Very tough to get an official answer.
 - 5. The Guardian, which the company was showing in Canada, does seem a lot better than the cumbersome physician CGMS. As I understand it, the sensors have been greatly improved for over a year now – indeed, I tried CGMS Gold and the sensor worked for seven (7!) days in a row, though it's labeled for only three. Quite valuable information and allowed me to see the power of full time real time continuous - I personally can't wait. <grin>

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4. **Upcoming diabetes/obesity-related conferences**

- a. **November 14, Designing an Accelerated Cure for Type 1 Diabetes: Integrating Biology with Bioengineering.** Symposium at Sunsun, Santa Barbara.
- b. **December 14-15: Consensus Development Conference on Inpatient Diabetes and Metabolic Control, Washington DC.** www.aace.org. This is one of those under the radar screen conferences that is going to be top rate and terrifically interesting and will read on the industry direction - amazing faculty. If you'd like an agenda, please let me know.
- c. **February 6-8, 2004, ADA 51st Annual Postgraduate Course.** San Francisco, CA <http://www.diabetes.org/main/professional/conferences/default.jsp>

- d. **April 28 – May 2: AACE**, Boston, MA.
- e. **May 1-4, 2004: Pediatric meeting**, San Francisco, CA.
- f. **June 4-8, 2004: ADA**, Orlando, FL.
- g. **August 11-14, 2004: AADE**, Indianapolis, IN.

Appendix 1: Quotes from thought leaders on the USA Today site

<http://cgi1.usatoday.com/mchat/20031112011/tscript.htm>

1. **Dr. James Gavin notes encouraging words on inhaled insulin:** “The good news about injections is that the needles nowadays are microfine and very sharp, so the degree of pain or discomfort is nowhere what it used to be just a few years ago. Things have really gotten better for insulin users. The inhaled insulin devices are still awaiting approval, but it is likely that they will come to market in the next couple of years or so. We do not expect the inhalers to completely replace insulin injections, but rather to complement them. Since the inhalers will be used for short-acting insulin only, any person requiring a long-acting, or basal, insulin (which will be most patients who are on intensive regimens), will still need an injection, even if only once-a-day. Continue to give encouragement and support to your son. He has much promise ahead of him.”
2. **Dr. James Gavin is encouraged by A1C visibility:** “This is a very important concept for people with diabetes. They now have a "number" that states the goal they are shooting for to assure that their diabetes is in control and their risks of developing complications minimized. For years, people have known what number their cholesterol should be to prevent heart attacks, and their blood pressure number to prevent strokes, but not until recently has it been possible to tell people with diabetes what their blood sugar number should be. The A1c test is now able to fill this gap. Everybody with diabetes or who is concerned about diabetes ought to learn more about this number. Of course, it should be strongly emphasized that people with diabetes urgently need their blood pressure controlled and their blood *cholesterol at a normal or near-normal level as well. However, good treatment starts with an A1c of <7%.*”
3. **Frank Vinicor, director of diabetes programs for the CDC, on the insulin pump:** “*For many people with diabetes, especially those with type 1 diabetes, who have a very active lifestyle, the "pump" has made a real difference. There are several pumps out there, and to use a pump, big time education is required, and lots of practice, along with a good knowledgeable doctor and nurse who know about pumps. It is not easy, but can be a great step forward.*”
4. **Frank Vinicor, on improvements in diabetes treatments:** “*While it is never good to have diabetes, it is better to have diabetes in 2003 than even 10 years ago - in 1993. We have better and purer insulins; better ways to give insulin; better ways to monitor the blood sugar that are not as painful, don't require much blood, and more quickly give the results.*”
5. **Frank Vinicor on non-invasive monitoring:** “*Lots of people and businesses are trying to find ways to measure blood sugar without having to prick the finger. The idea of using changes in skin electrolytes, or things like that to determine the blood sugar are being explored. The "GlucoWatch" has been approved by the FDA but for kids at night to detect low blood sugars. It still requires things be "calibrated," that is finger sticks still need to be done. But these sorts of things are being worked on very hard, and should be available in about 2 years. Research is progressing very rapidly, and the possibilities of cure could be available in 10 years.*”
6. **Frank Vinicor on continuous monitoring and other prospects:** *Again, it is not easy to have diabetes, or to be the parents of a youngster with diabetes. But there are very active studies underway to see if insulin can be given as an inhaler, e.g. like asthma is treated; or perhaps even in a special pill by mouth. Also, they're very exciting developments in ways to measure the blood sugar constantly over many days without having to prick the finger. And of course, there is lots of excitement about transplanting insulin producing cells back into the body of someone who has lost their cells - usually someone with type 1 diabetes.*”

Appendix 2: Washington Post, November 10, 2003

Washington Post Examines Potential 'Disease' Classification for Obesity"

The Washington Post on Monday examined the "intense debate" among federal agencies, insurers, pharmaceutical companies, advocacy groups and scientists to determine if obesity should be considered a "disease." Such a classification could hasten the approval of new medications and boost coverage for millions of people for treatment of weight-related problems. According to the Post, the momentum to label obesity as a disease "appears to be accelerating." The NIH and the World Health Organization have already made the decision that obesity should be thought of as a "distinct disease entity," and last year, the IRS declared obesity as a disease, allowing taxpayers to deduct health expenses related to obesity for the first time. Currently, CMS is reviewing whether it should also classify obesity as a disease, which would result in coverage of some weight-control therapies for Medicare and Medicaid beneficiaries without other health problems for the first time and put pressure on private insurers to follow suit. The Agency for Healthcare Research and Quality presented a report that outlined evidence on both sides of the arguments in September, and CMS is expected to make a decision soon. The FDA is also reviewing whether it should evaluate diet drugs on an accelerated basis. According to the Post, FDA Commissioner Mark McClellan said that FDA meetings with drug companies and the American Obesity Association are "likely to result in revised guidelines for testing diet drugs." He added, "This is an important enough problem ... that we want to make sure our regulatory process is up-to-date as possible. We really need those treatments."

Reaction

Proponents of the classification say that "new scientific understanding" has proven that obesity is a medical condition and that the label would both help destigmatize the condition and eliminate economic and regulatory obstacles to treatment and prevention, the Post reports. Morgan Downey, the executive director of American Obesity Association, said, "For ages, obesity has been regarded as a personal moral failing -- a behavioral issue that's easily fixed by people who have sufficient willpower to do so. The modern scientific understanding of obesity is that it is a complex disease in its own right." However, opponents say that obesity is more similar to a risk factor -- such as cigarette smoking or high cholesterol -- that predisposes someone to illness than a disease and that classifying obesity as a disease would take "scarce resources, distract public health efforts from the most effective countermeasures and unnecessarily medicalize the condition," the Post reports. Tim Church, the Medical Director at the Dallas-based Cooper Institute, a not-for-profit exercise-focused research group, said, "You can be overweight and healthy if you are active," adding, "You could say that if obesity is a disease, then not enough exercise is a disease or not eating right is a disease" (Stein, Washington Post, 11/10).

Appendix 3: Survey detail

A survey was conducted in October with 500 American adults with type 2 diabetes – while this isn't a very large scientific survey, still of note - nearly half didn't have any idea of what a good score is.

1. **Many are uninformed** ... Nearly half didn't have any idea of what a good score is. (44% of those surveyed had heard of the A1C test – when described, 45% knew their level. Of those, 23% reported a score <7%.)
2. **Hope springs eternal** – maybe it's just a learning curve. 73% of people under age 45 were aware of A1C compared to 30 percent of those 65 or over. Similarly, 78% of those under 45 had their A1C tested in the last year, compared to 54% of people age 65 or over. That no great shakes though – it's supposed to be 4x/yearly!
3. **Delusion persists:** The USA Today piece cited a recent ADA survey that found over half of overweight people interviewed characterized obesity as a major risk factor for diabetes, but 59% said the personally were not at risk. That's sort of like how 95% of my business school class characterized themselves as above average.

Appendix 3a - Final observations: I just read *W;t*, by Margaret Edson. If you need a dose of reality, pick this up and read it tomorrow – it only takes an hour and lends real perspective.

Diabetes Close Up is a newsletter highlighting notable information and events related to selected companies with diabetes/obesity businesses. This newsletter is put forth as an unbiased commentary on the industry. If you have any suggestions or comments regarding content, please contact info@closeconcerns.com. If you would like to 1) unsubscribe; 2) receive a monthly digest rather than real-time updates; 3) add a name to the DCU mailing list; or 4) offer any suggestions or comments regarding content, please contact info@closeconcerns.com.

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