

DIABETES CLOSE UP

Diabetes Close Up, V3, #10
June 2, 2004
TIME on Obesity ~ Industry Update

T h e s h o r t v e r s i o n

1. **TIME Obesity meeting - impressive:** TIME Magazine/ABC News is sponsoring an impressive meeting on obesity this week (see www.time.com/obesity) that began yesterday in Williamsburg, VA. All the major leaders are here and they've put together an incredible agenda – we think it's excellent that they are attempting to raise awareness to the problem that just won't stop.
 - As I prepared for the trip here, a few observers (read: cynics) questioned “yet another meeting on obesity,” noting that the subject has really taken off as the hyped health issue and wondering aloud what could be new to say or if it's possible that any solutions exist at all. I couldn't help but be a little jaded hearing doubts, but no one could argue that the lineup wasn't superb and I must say after the first half-day, it's a really stellar meeting with truly actionable initiatives being discussed.
 - See inside for a quick overview of highlights from the first day.
2. **Congress on Obesity:** Turns out there's a Congressional hearing Thursday morning - “The Supersizing of America: The Federal Government's Role in Combating Obesity and Promoting Healthy Living” on the federal government's role in combating obesity. “*It could get feisty,*” says Martha Nelson, DCU researcher/writer just back from Southeast Asia in time for ADA. Martha will cover the hearing before coming down to Orlando and we'll have in depth reports on both the TIME obesity meeting and this congressional session later in the summer – after we cover the ADA, the bariatric meeting in San Diego, and Endocrine Society, all of which will take us nearly to July 1.
3. **Industry Update: CoZmonitor ~ Medtronic MiniMed ~ Animas**
 - a. Abbott Diabetes Care/Smiths Deltec garner approval for CoZmonitor yesterday (June 1)
 - b. Medtronic MiniMed reports fiscal 4Q04 last week
 - c. Animas goes public in May

The longer version

1. **TIME/ABC News on Obesity:** Notable goings-on from Day 1:
 - **Secretary of Health and Human Services Tommy Thompson** opened the session today and just as director extraordinaire Morgan Spurlock is doing with Super Size Me, he, and TIME are bringing fantastic awareness to this most unsettling issue and it seems there's a chance that some of it is sinking through to people. *Bottom line, true, nothing has changed, it's still about eating less and moving more* – but the public is becoming considerably more educated about what the implications of ignoring obesity are. You can tune into the webcast for the rest of the meeting at www.rwjf.org/news/eventDetail.jsp?id=1083787982803&contentGroup=webcast (through Friday ~12 noon EST).
 - **Some of the facts and findings we heard/read are truly unsettling:**
 - By age 17, kids on average have spent 38% more time in front of TV than in school
 - 58% of Americans want to lose weight, but only 26% exercise regularly and only 6% closely watch fat, carb, and calorie intake
 - In the year 1700, it's estimated that British citizens consumed 7.5 pounds of sugar per capita, while in the US today, we consume over 150 pounds of sweetener per capita (nearly half which is high-fructose corn syrup);
 - Every additional daily serving of a soft drink increases a kid's risk of becoming obese by 60% - to boot, on average, teens get 10-15% of daily calories from soft drinks;
 - For every hour of TV watched a day, obesity risks for children increase 6% ~ for every hour people spend in cars, they are 6% more likely to be obese
 - Only 28% of kids that live within a mile of school walk there (17% of kids total)
 - Ads for high-fat, high-salt foods are now more than 2x what they were in the 1980s; kids see 40,000 TV ads per year, double the 1970s rate
 - 25% of vegetables eaten in US are French fries
 - The average burger in 1957 weighted 1 oz (210 calories) vs 6 oz (618 calories) today
 - 44% of people questioned (n=1200) said that it was difficult to walk to *any* (emphasis added) destination from their home
 - **BOD, please:** Several of the talks this afternoon were incredibly inspiring, such as Risa Lavizzo-Mourey, MD, President and CEO, the Robert Wood Johnson Foundation, and Majora Carter, Founder and Executive Director, Sustainable South Bronx. Two powerhouse woman who you really do believe could change the world (they should be elected to lots of BODs) – details to come in our longer report.
 - **On sit-ups and pedometers:** Secretary Thompson has lost 15 pounds recently and said that he forced himself to start doing sit-ups every morning and every night – hard core. Check it out, he is now doing 60 every morning and 60 every night. He also is obsessed with his pedometer. It sounds geeky, but I love mine too – if you come to ADA this year, you'll probably be given about ten free ones, as they are very popular this year (last year, Abbott was the only exhibitor to give them away). My favorite is Nike's SDM Tailwind.
 - **The best thing from this issue of TIME? Marion Nestle's immortal words: *eat less, move more, and eat fruits and vegetables.*** We'll be back with the most interesting new facts on this subject gleaned from this excellent conference in July, along with news from Congress, if there is any(see Appendix for panel lists).
2. **Industry Update #1: CoZmonitor approved yesterday, June 1:**
 - **Yesterday (June 1) Smiths Medical (Deltec parent – now using Smiths name), announced the FDA 510(k) approval of the long-awaited CoZmonitor accessory for its Cozmo insulin pump.** The CoZmonitor uses existing robust Therasense FreeStyle blood glucose meter technology and the same Therasense test strips already produced for the Therasense FreeStyle and FreeStyle Flash meters. The CoZmonitor's MSRP of \$99 may be picked up by patients' insurance companies – unclear just yet, but if someone wants it, for this price, they'll snap it up in our view, subsidy or not. The CoZmonitor functions only when attached to a Cozmo pump: it cannot be used separately or with any other pump.

- **Therasense, recently acquired by Abbott, may stand to make small gains in market share** from current Cozmo pumpers ditching meters from other makers in favor of the CoZmonitor. While they may gain only a small number of actual real customers compared to their base, pump patients are among the most valuable patients as many use upwards of 6-8 strips per day, well above the less-than-two average of all patients with diabetes in the US.
 - **At the ADA, we'll look to find out all the good stuff** like where patients keep their lancets, lancing devices, strips etc. (not in a meter case!).
 - **Our one question – why did this take so long at the FDA?** Despite good intentions (?), the agency appears to be moving seriously slowly on new approvals from what we can see. Sometimes, we wonder, how big a priority diabetes really is. At a recent FDA_NIH meeting in Washington, a leading scientist from one of the top biotechnology companies asked in Q&A where the agency rated the severity of diabetes, “on a scale of 1 to 10” compared to say, a disease like cancer. Very intrigued, I looked up, while the room got quiet. Unfortunately, there was no answer but shuffled papers.
 - For more information, see <http://www.cozmore.com>.
3. **Industry Update #2: Medtronic MiniMed reports fiscal 4Q04 last week:**
- **Despite recent troubles with disposables¹, Medtronic MiniMed reported a strong quarter.** Sales rose 24% year over year to \$150 million at MiniMed; pump sales rose 25%, while disposables increased ~23%. Sequential sales rose ~4%.
 - **Those who say the pump market is slowing seem off target.** In fact, we believe it'll continue to grow at a nice pace particularly as we come closer to continuous monitoring, when patients will, we believe, with that technology, begin iterating insulin dosing more and more frequently. We believe that the entire pump industry has innovated much more quickly in the last couple of years, ultimately benefiting patients and families.
 - **New pumps enable much greater control** over glycemic variation than earlier models. To boot, they are smaller and considerably lighter, big advantages in our view.
 - **Competitive notes:**
 - **Medtronic** remains the market share leader in the US, although profitability took a recent hit as a result of its recent Class 1 recall, where the company pulled its Quick Set Plus disposables from the market recently. The recent troubles with MiniMed disposables (and other problems with Disetronic disposables and Nipro recalls, to a lesser extent) hurt the entire industry. What impact these problems will have remains to be seen; pump patients only replace their models every 4.5 years on average, so even a very upset disposable buyer will almost certainly stay with their current pump at least until replacement time is up. Thus, the risk of losing customers is more long term than short term oriented and difficult to quantify.
 - **Currently, Animas'** (Nasdaq: PUMP) IR1200 is the smallest, lightest pump on the market and is garnering excellent reviews from patients and healthcare providers.
 - **Roche/Disetronic** is the market leader in Europe. Medtronic MiniMed says its business is growing much faster outside the US, from a smaller base. “There's way more market to penetrate outside the US.” Although it was estimated that Roche/Disetronic would return to market by mid-year, we now believe later in 2004 is more likely. On the continuous monitor front, trial results for the cBG monitoring (GlucoOnline) are expected take 12-18 months to complete.
 - **Medtronic's chatter on the artificial pancreas continues.** CFO Bob Ryan noted that progress continues on external and implantable insulin pumps and continuous glucose monitors as the company drives to develop an artificial pancreas. Medtronic has used the phrase “artificial pancreas” much more frequently of late. Too, they say there will be “interesting developments” in diabetes franchises ...
 - **FDA notes:** The Company had sited end of FQ4 as the deadline to submit its “real-time” monitor, the Guardian 2; perhaps we will see more about this at ADA. Specifically, the company said that by fiscal year 2008, “or perhaps sooner,” the artificial pancreas will become a reality in diabetes.

¹ See DCU V3, #7 from March for more details on this topic

4. **Industry Update #3: Animas** (Nasdaq: PUMP) **is now public**, as of May 19. The company had a very successful IPO, pricing at the top of the \$13-\$15 range, raising \$63 million, and closing at \$18 at the end of the first day of trading and just under \$20 yesterday.
5. **Appendix: Congress on Obesity – June 3.** The hearing will begin upon conclusion of the Business Meeting scheduled for 10 am.

WITNESS LIST

PANEL ONE

Dr. Lester M. Crawford
Acting Commissioner
Food and Drug Administration

Mr. Lynn Swann
Chair
President's Council on Physical Fitness and Sports

Dr. Eric Hentges
Director
Center for Nutrition Policy and Promotion
U.S. Department of Agriculture

PANEL TWO

Dr. Arthur Agatston
Cardiologist and Author of
The South Beach Diet

Dr. Stuart Trager
Chairman
Atkins Physicians Council

Dr. G. Harvey Anderson
Professor, Department of Nutritional Sciences
University of Toronto

Dr. Susan Finn
Chair
American Council for Fitness and Nutrition

Mr. Bruce Silverglade
Director of Legal Affairs
Center for Science in the Public Interest

+++++

Many thanks to Melissa Ford, Martha Nelson, and Stephen Simpson in researching and writing this newsletter.

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.

Disclosure: Kelly L. Close is a specialized consultant to the medical technology/pharmaceutical/biotech industries. Companies 1) in which Kelly Close has a personal investment; and/or 2) that are clients of Close Concerns, Inc. include Abbott Diabetes Care, Animas, Amylin, DiObex, and Inamed. All observations expressed are the opinions of Close Concerns alone and should not be viewed as recommendations to investors on any companies in the industry.