CLOSERLOOK

Consumer Electronics Show 2011 – Digital Health Summit

January 6, 2011; Las Vegas, Nevada; Highlights – Draft

Executive Highlights

We attended Las Vegas' annual International Consumer Electronics Show yesterday, which this year included a special day-long Digital Health Summit. By way of context, CES is ten times bigger than ADA; there were over 120,000 attendees this year and 2,700 exhibitors, the city's hotel rooms were completely sold out, and Friday's "Digital Health Panel Discussions" were standing room only with a line out the door to get in.

The most interesting discussion on digital health focused on mobile health and included rising star and president/COO of WellDoc Anand Iyer; Bradley Merrill Thompson, an attorney who has led efforts to standardize FDA regulation for medical devices; David Haight, VP of Business Development with AT&T's Emerging Devices Organization; and David Inns, President and CEO of GreatCall, the makers of Jitterbug cell phones and several mobile health apps. The discussion was transparent, candid, and informative in a field that is garnering growing attention. In our view, a perfect storm is forming in diabetes: costs continue to climb, adherence to therapy and lifestyle changes remains low, and patients don't have optimal attention from healthcare providers. The panelists proposed mobile health as a solution to these problems – a low-cost way to give patients more information and foster greater engagement in the day-to-day, on a device that they already own and use. There certainly seems to be a great deal of interest building at larger companies in what role mobile health can play and very smart people have clearly been charged at the top companies (pharma, medical technology, payers) at thinking about behavior change. We will be interested to see if and how momentum continues to build and how companies address (buy or build?) perceived skill gaps on several fronts – namely social, mobile, design, and user experience. Creating access to devices, capabilities for patients to manage them, and useful user experiences seem important building blocks.

Another interesting theme on digital health was embedding cellular radios into basic medical devices to ensure that devices are always connected to the Internet for monitoring, alerting, etc. This could have notable implications for diabetes and obesity (CGM, pumps, etc.).

At the exhibit hall, we visited the booth of Ideal Life, featuring a new display tablet that allows patients to answer health-related questions and to video-conference with healthcare providers, a potentially valuable complement to the company's Bluetooth-enabled monitoring products (including a glucose meter). We also looked at the booth of BodyMedia, featuring a new Bluetooth-enabled armband and Android phone app so that users can access the system's diet and exercise analysis on the go (for more on BodyMedia, see our "Test Drive" in diaTribe #25- http://www.diatribe.us/issues/25/test-drive.php - September, 2010). Although the digital health field is young, the early entrants have shown potential to reduce systemwide costs and improve patient outcomes. We think that if the regulatory and reimbursement environments are favorable, there could be significant growth in this field for small and big companies alike and that at next year's CES, there will surely be more than a day devoted to healthcare. As it was, though, a very energetic start.

Highlights

The Doctor in Your Hand: Exploring Mobile Health Options

- **Bradley Merrill Thompson, JD, MBA (Epstein Becker & Green, P.C) discussed the regulatory environment for mobile health, focusing on the uncertainty surrounding the FDA.** He described a common scenario that "has been breaking my heart, quite honestly" of late: when his clients learn that a new technology is likely to be regulated by the FDA, they often back out of investing. For these would-be investors, FDA regulation is seen not only as a huge additional cost, but also very challenging to "read" – understandable given the ambiguity of existing FDA regulations and the novelty of emerging technologies. As general counsel to the Combination Products Coalition and mHealth Regulatory Coalition, Mr. Thompson has worked with industry and other stakeholders to develop policy recommendations for future FDA regulation. In fact, he mentioned that he and his colleagues are meeting with the agency on Monday to lay groundwork for a mobile health regulation proposal that they hope to write and submit for adoption by the spring of 2011. Major topics include: what usage claims are regulated by the FDA, what pieces of hardware are regulated as "accessory" devices, and what level of software functionality will trigger FDA regulation. (Mr. Thompson explained that the FDA has said it is too busy to develop its own policy but will consider external proposals. His comments reminded us yet again that the FDA is too under-resourced to fully address many key issues or to offer salaries that are competitive with those of industry – a major challenge given the agency's many key responsibilities.) On a side note, Mr. Thompson cautioned against assuming that Medicare will approve new technologies. He reminded the audience that some health-related actions (e.g., buying fruits and vegetables) do not fall under the government's purview, and he stressed that technologies must be clinically proven before they gain insurance coverage – even though in his experience, many entrepreneurs wish reimbursement could come first!
- **Anand Iyer, PhD (President and COO, WellDoc) advocated health technologies based on the cell phone (which "knows no socioeconomic, literacy, or language boundaries")** as a way to foster patient engagement and improve patient-provider interactions. As someone with type 2 diabetes, Iyer vividly characterized seeing a blood sugar of 168 mg/dl before eating lunch as akin to hearing on the car radio that "all the usual ways home have been closed due to construction or accidents". Both are complex scenarios that require actionable information – something that is often lacking in today's healthcare environment. Dr. Iyer noted that single physician visits often give an incomplete picture of glycemic control; he joked that his own past glycemic variability ("blind, coma, blind, coma") could translate to an average A1c and not be noticed. In addition, Dr. Iyer said that even when patients are highly engaged and share graphs of their data, healthcare providers aren't able to make sense of complex patterns in the short time of a typical visit – and given no reimbursement for such analysis, this is a challenge indeed. Thus, he argued that an important niche exists for automated real-time feedback of the sort offered by mobile health systems. Dr. Iyer proposed that reimbursement of these systems will likely vary depending on whether technologies are assessed in terms of cost savings or in terms of efficacy relative to existing treatments. He noted that WellDoc's system led to mean A1c reductions of roughly 2.0% in clinical trials – "triple the A1c drop of Merck's Januvia [sitagliptin]" – and he said that other promising results will be forthcoming from WellDoc's yearlong clinical trial (see Closer Look, August 23, 2010). As for clinical trials, Dr. Iyer observed that the FDA requires repeated demonstrations of efficacy. ("Why is it that we send a man to the Moon once and everyone believes, but we have to do a hundred million trials of the same freaking

thing?"). Of course, "second and third order effects" must be taken into consideration with due scientific rigor. However, he applauded the FDA and Commissioner Margaret Hamburg for their efforts to address unprecedented regulatory issues in mobile health. He told how the agency originally discussed the need to submit separate approval requests for every single cell phone model that could integrate with the company's software. WellDoc countered that three general models (those with traditional keypads, or QWERTY keyboards, and touch screens) would need to be tested to minimize patient-induced risks. Ultimately, the FDA accepted this argument – to Dr. Iyer, a positive sign that the agency is coming to understand mobile health and that companies should continue working with the FDA on a viable path forward.

- **David Haight (Vice President, Business Development, Emerging Devices, AT&T Mobility) emphasized the need to treat patients as consumers, providing them with multiple choices of how to engage with the healthcare ecosystem.** As an example, he mentioned AT&T/Vitality's GlowCaps, the Internet-connected pill-bottle tops that alert patients when they should take medicines and record compliance data. Mr. Haight outlined several ways that GlowCaps could be delivered – by pharmaceutical companies seeking to improve adherence and expand business; through AT&T; or on the shelves of Walmart, where many patients already go to fill prescriptions.
- **David Inns (President and CEO of GreatCall, Inc.) forecasted that, in order to fund customer support, mobile health companies will move away from a one-time download model to a monthly fee model (like that used by GreatCall).** He noted that a major challenge for mobile health companies is the one faced by all consumer marketers – awareness among potential customers.

-- Joseph Shivers and Kelly Close