

## There's an APP for That!

### Technology Key Enabler to OTC Statin Switch

Apple revolutionized the music world with the iPod. Who will revolutionize the switch world? From our perspective, that market innovator will use today's technologies to unlock billions of dollars of market potential.

BY SUSAN BABINSKY

➤ With Pfizer's highly successful Lipitor now going off patent in November 2011, the opportunity for such a well-known brand to move to OTC status has been widely speculated, yet the likelihood of switch dismissed given past failures to gain FDA approval for statins. Indeed, there are key obstacles any company will face if they attempt to switch a statin, or for that matter, any product designed to treat a chronic, asymptomatic condition. From our view, these obstacles can be overcome, and that the right vision along with technology can become a major game changer in the world of Rx-to-OTC switches. ... It allows consumers to make complex decisions quickly, accurately, and in an orderly manner.

#### WHAT TECHNOLOGIES ARE NEEDED?

**1. Cholesterol Testing:** A full lipid panel including LDL and HDL cholesterol should be analyzed. At the present time, this test does require a drop of blood, but newer technologies are being developed that measure skin cholesterol levels from a person's palm. This test can be performed at a lab, pharmacy, or kiosk. There are also home test kits where consumers can mail in blood samples to be analyzed.

#### 2. Cardiovascular Medical History:

A series of questions regarding a consumer's pertinent medical history, including age, gender, use of prescription cholesterol lowering medications, history of liver disease, stroke, or diabetes, use of a few prescription drugs that interact with statins, potential to become pregnant, and smoking history. There are numerous technologies and platforms to collect these data electronically, such as the Internet, kiosks, and smartphone applications.

**3. Monitoring of Therapy:** Monitoring of therapy consists of subsequent cholesterol tests to ensure cholesterol targets are being met. There is also a need to track and encourage persistence and compliance, as well as a need to monitor for side effects, especially unexplained muscle pain. Numerous technologies have been developed to monitor and track the treatment of Type 1 diabetes and other chronic conditions which can be leveraged for cholesterol monitoring. Furthermore, smartphone applications have been developed to make monitoring even more effective and convenient for consumers.

**4. Distribution:** Once eligibility is determined, a system that ensures only those who qualify receive medication is needed. Once again, technologies are already in place that allow for restricted access. For exam-

ple, mail order pharmacies

have perfected fast and efficient distribution systems. In the retail setting, several companies have already gained experience dispensing OTC products through kiosks in various locations. Retailers also have the ability to control access through their customer databases – which can include designations for approved consumers – with purchase validation achieved through personal identification verification (for example, the CVS ExtraCare card).

The race is on in the switch world to develop a system that can integrate all of the components into a simple, consumer friendly platform. As with all endeavors involving regulatory approval, the risks are high and the costs are not insignificant. On the flip side, the pioneering company with the vision to bring it all together would be first to market and have a huge competitive advantage.

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