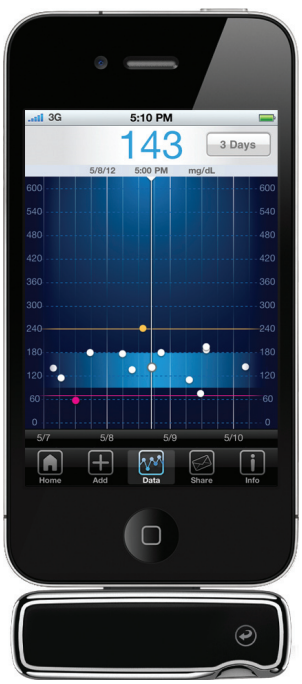
Anne Whitaker, president, North America, pharmaceuticals, Sanofi

PHOTO: BILL BERNSTEIN

THE APP AVANT-GARDE

Medical devices marrying apps and consumer electronics are setting off a wave that will revolutionize chronic-disease management—and could upturn biopharma business models, **Matthew Arnold** reports



Sanofi and AgaMatrix's iBGStar

Imagine a patient with type 2 diabetes plugs a port little larger than a thumb drive into her iPhone and inserts a test strip. Up pops a three-digit number—her blood-glucose level. She logs it, emails it to her doctors, and when she goes in for her checkup, her endocrinologist can spot a pattern of spikes and troughs over days, weeks and months and advise behavior changes or rebalance medicines accordingly. It's as intuitive and seamlessly designed as the iPhone itself.

The future is here. The device-plus-app-for-iPhone launched last month in Walgreens, on iTunes and in bricks-and-mortar Apple stores alongside several other monitoring devices for iPhone.

Sanofi and AgaMatrix's iBGStar is one of the advance guard of a new breed of medical device—one that's part app and part gizmo and interfaces with smartphones to allow patients with chronic conditions like diabetes an easy, DIY way of monitoring their health and sharing that data with their doctors. It's a tool tailor-made for this era of Big Data, empowered patients and ever fewer primary care physicians, who have less time.

It also suits the pharmaceutical industry's shift toward a more diversified offering featuring not just drugs and biologics but also diagnostics, devices and services, bundled together to give their therapies an edge with increasingly powerful and tightfisted payers—in Sanofi-speak, "Moving beyond the molecule."

"IBGStar is our first step forward in going beyond insulins and medicines for the patients and really delivering a more integrated solution," says Anne Whitaker, president, North America, pharmaceuticals at Sanofi. "As I go out and talk with the various health plans, what they're all aimed at is becoming more patient-centered and delivering better outcomes for their patients. And they're looking at who can be the best partner. They're looking at the type of company that comes to the table and what their intention is, and I think by showing up with a more comprehensive solution, we're demonstrating that we're putting the patient at the center."

There are around 26 million Americans with diabetes, according to CDC estimates, including 7 million who are undiagnosed. Those that are on therapy aren't getting a lot of time with their doctors, and their doctors aren't getting much information about their patients' health.

"There's simply not enough physicians to keep up with something like diabetes," says Sanofi's Dennis Urbaniak, VP US diabetes. "Endocrinologists are a relatively small number and primary care doctors bear the burden of care for people living with diabetes, but their time is severely compromised…The typical person with diabetes spends six hours a year with their primary care provider. After that, they're left on their own, trying to live with this very challenging and complex condition."

Mobile disease management promises to fill in that in-between time, to connect the dots through well-organized streams of longitudinal data.

"Doctor-patient facetime is where most pharmaceutical products focus their marketing efforts," says HAVAS Health chief digital officer Larry Mickelberg. "Now they've got to think about the in-between time, and that's where innovation is going to happen. It's a characteristic difference between the old healthcare mindset and the way things are moving, and that means rather than periodic exchanges of information between doctor and patient during scheduled visits, all parties can now consult and exchange information in a continuum across multiple channels."

Sanofi execs are quick to say that this isn't a play for the blood glucose monitor market—nor do they expect to turn much of a profit off the iBGStar, currently going for $74.99 at Walgreens. Rather, it's a down payment on a new business model and a means of acquiring expertise in this sort of mobile disease management, skills which may be transferrable to a number of chronic conditions, from heart disease to COPD to pain management, even oncology.

"The strategy of this more diversified platform is one that we see a lot of applications for in multiple therapeutic areas," says Urbaniak.

WellDoc raises the bar

WellDoc built the business model for its buzzy DiabetesManager super-app around third-party reimbursement. The service is currently marketed to employer groups and HMOs through AT&T, although WellDoc plans to launch a patient version, available through physicians' offices, around the end of the first quarter in 2013.

Withing's iPod-integrated blood pressure monitor (above), one of several mobile medical devices to pass muster with FDA; WellDoc's Diabetes Manager app (below) also has approval

"There's value here that's different, obviously, than just creating a free or 99 cent app you can download off iTunes," says WellDoc's Demir Bingol, VP of commercial marketing.

DiabetesManager was the brainchild of Dr. Suzanne Sysko Clough, an endocrinologist at the University of Maryland's Joplin Diabetes Center. Smartphones weren't yet in circulation, but Dr. Clough observed that all of her patients, regardless of socioeconomic status, had cell phones, and started looking for ways the devices might be used to help patients self-manage their condition.

"At every step along the way, they would hear the usual thing most innovators hear," says Bingol. "'No', or 'It can't be done. No one's ever going to use a phone to self-manage their condition. You'll never get it cleared through the FDA.'"

To the contrary, the FDA granted WellDoc 510(k) clearance to market DiabetesManager as a Class II medical device to adult type 2 diabetes patients and care providers back in 2010. The company then put some numbers behind its boasts with a clinical trial, showing an average decline in A1C levels of 1.9 percentage points, besting the 0.7-percentage-point decline in the control group, as well as most of the top-selling medicines on the market. A 12-month survey of 32 Medicaid patients found that the system reduced ER visits and hospital stays by 58% over the previous 12 months.

"We are starting to see more companies conducting bona fide clinical trials for their software products, including mobile apps," says LifeScan's Joe Shields. "It's a big step in the right direction—if you are going to make medical claims about apps or software, you must provide appropriate clinical support. This is an area where I think medical software and device companies can look to pharma for other examples of how to build clinical trials and work with large volumes of data in order to support the claims they want to make about their products and services. This applies to health outcomes claims as well, which of course payers are very interested in."

DiabetesManager collects data on the patient's diet and exercise, blood glucose and medication regimen, then uploads that information to the cloud and runs it through WellDoc's proprietary analytic engine. The system provides automated feedback to the patient based on that data in the form of alerts, prompts and positive reinforcement.

"It learns about the patient as it goes and responds to them in a way that's meaningful to them," says Bingol, adding that "we are cleared by the FDA for real-time coaching and feedback for the patient and clinical decision support for clinicians."

Patients can turn up or dial down the feedback loop at will and loop in whomever they like. Doctors can collaborate with the patient on goal setting, even upload their own content, including video, for the patient.

The program maintains a personal health record that could easily be piped into an electronic health record system—WellDoc has already done a pilot EHR program with AllScripts. And the firm's platform looks to be similarly portable, capable of being plugged into disparate disease states and vehicles—maybe even a car from Ford, with which WellDoc has been in talks (Ford is also working with Medtronic on an in-car glucose-monitoring system that uses its SYNC technology).

It's a preview of the always-on health monitoring systems to come, in which everyday objects—cars, toilets, bicycles, eyeglasses—may one day discreetly gauge our blood pressure, blood glucose and other indicators around the clock, giving physicians and nurses a steady stream of neatly-packaged biometric data.

"We already live in houses and drive cars with monitored security systems," says A. J. Triano, VP of mobile engagement at Ignite Health. "It's an easy extension to foresee a world where our doctors use smart technology and powerful data filters to monitor our care remotely, reducing the need for face-to-face visits."

The market for these devices is mostly in wealthy nations for now, but they hold the promise of enormous impact on global health. Jim Walker, director of emerging tech at agency Cadient, notes that there are smart phone add-ons in development that could detect melanoma, malaria or cataracts. "If we fast forward a few years, as the phones get even cheaper, it could really make a difference all over the world. Health workers could go out and test for malaria right there in the field."

A French cuff to accessorize your iPhone

There are a couple factors besides the technology holding up that future. One is the current lack of an EHR standard. Forget VHS vs. Beta, Apple vs. PC or Blu-Ray vs. HD DVD—the battle for EHR supremacy is a free-for-all brawl among a dozen players.

"There's a lot of trepidation because of that fact," says Jim Dayton, senior director, emerging media at agency InTouch Solutions. "There are just too many proprietary companies all vying to be the standard, and until that's decided, I don't think we'll see pharmas jumping on this too quickly."

The regulatory process can be daunting, too, even for drug and device companies familiar with the approvals process. The FDA issued draft guidance last July on mobile medical apps, exempting most of the more marketing-centric apps from pharmaland—disease journals, tracking logs, carb counters and the like, most anything that does not traffic in patient-level data—from scrutiny, zeroing in on those apps which "are used as an accessory to a regulated

PATIENT POV


Scott Benner


Amy Gurowitz


Andrea Martin


Jackie Zimmerman

Four health activists were assembled by Wego Health to represent the patient perspective, and asked for their opinions of iBGStar and other personal devices and apps.

Before being shown the iBGStar, panelists were asked about the general state of health apps that run on mobile phones to collect health data and help them understand it.

"For me, coming from an MS perspective, I've not yet found a mobile app that I'm happy with," says Amy Gurowitz, author of the blog MSLOL.me and MS Soft Serve, a non-profit, online learning tool for people with multiple sclerosis.

Her constituents aren't luddites, but are "waiting and seeing if anything good is coming out," Gurowitz says. She laments the "cookie cutter" approach and lack of flexibility of those she has seen.

Jackie Zimmerman, a health activist for the MS as well as Crohn's and Colitis communities, is not shy about trying new ways to manage her health. "I am the epitome of a millennial," she says. "We are 100% early adopters." But Zimmerman, who blogs at BloodPoopTears.com and the MSUnderstood blog (themsblog.com), says "nothing has met my needs or done enough of what I'm looking for."

Connected and customizable apps got our health-activist panel's collective thumbs-up. Most pharma apps work in silos, they say. What's needed are apps which integrate—either with other apps or devices, if appropriate for that disease state, and offer personalization for multiple illnesses.

Apps that do a good job of documenting vitals and dosing have an added benefit: "I had to go to six doctors to [get one to approve my] endometriosis surgery," recalls Andrea Martin, a chronic illness activist and author of the "It's Time to Get Over How Fragile You Are" blog (fragileannie.com). "If [an app] would have been able to show them I had tried everything, I think I would have had more success."

As far as the $74.99 iBGStar, which combines a disease-management app and an iPhone-enabled blood-glucose tester, the device design is "a huge step in the right direction," says Scott Benner, who speaks from his experience caring for a daughter with type 1 diabetes. Time will tell whether the app improves on the usability of existing monitors, which he says seem like "whoever imagined collecting and showing the data was an engineer and not a person with diabetes or [a caregiver]."

Respondents also applaud the ability to e-mail information to the doctor, as well as the free counseling and coaching portion, which, Gurowitz points out, enable users to develop a personal health plan and with it a certain amount of control. "Patient control is so important because none of us feel like we have control when we're sick," adds Martin.

But its price tag could put off chronic illness sufferers, many of whose monthly budgets are maxed out on medications. "You're narrowing the focus with that," warns Gurowitz, who says MS community members are angry to begin with about drug prices. "As with anything pharmaceutical, I think there should always be a very well-represented affordability and for people who can't afford it, an assistance program… Whenever there's a price tag associated with anything, it better be good."

The race for a wearable wellness tracker

Makers of medical apps and mobile health devices are keeping a close eye on two entrants from the consumer-facing health and wellness world—Fitbit's Ultra Wireless Tracker and the Nike+ FuelBand. At first glance, they look like souped-up pedometers, but they're much more than that and they come pre-wired for the electronic health record revolution.

Fitbit, which looks something like a futuristic clothespin with a digital display, has actually been around since 2008. Users can input information on their diet, weight, body fat, heart rate and glucose readings through the Fitbit website. It tracks movement and sleep. As with WellDoc's DiabetesManager or Sanofi's iBGStar, users can share information easily.

"If you have all that data on yourself, you essentially have your own EMR within the Fitbit system," says InTouch's Jim Dayton. "But they've also been very smart and made open APIs for other applications like Microsoft HealthVault, so you can port your data over there and if your doctor uses HealthVault, it's right there for them. When my doctor saw the Fitbit and the data I was collecting, he said 'This is awesome. I can keep this right here in your record and I can actually practice preventive rather than reactive medicine because I can see what you're doing.'"

Then there's Nike's FuelBand, a chunky black bracelet that tracks movement and caloric burn and then game-ifies exercise by awarding you Nike Fuel based on your day's exertion, urging you to set and beat goals. The company calls it a "scoreboard for your wrist." As with Fitbit, the data FuelBand collects is beamed up to the cloud so it can be accessed through the website—or ported to an EHR.

"I think something like that has incredible sticking power," says Sanofi's Dennis Urbaniak, VP US diabetes. "The growth in that app and the way it's being used, from run tracking initially to, now, broader overall exercise management, is very interesting."

Jawbone's UP is another newer entrant in the race. UP's wristband is a little more discreet than The Swoop's. It tracks movement, sleep patterns and nutrition, along with an accompanying app and program that takes a social bent. Launched last year, UP got off to a glitchy start, and Jawbone, better known for its Bluetooth headsets and wireless speakers, had to issue a money-back-no-questions-asked guarantee. But the product's social media-centricity sets it apart from Nike and Fitbit.

FuelBand, launched in January, is headed that way too, though. It's part of a Nike+ line including a sportswatch, an iPod Nano with built-in pedometer and a GPS app for smartphones, all of which will generate NikeFuel, which a spokesperson described as "a standardized metric in which you can compare activity in an intuitive and motivational way with other people" and allowing "everyday athletes to compare themselves with each other or with elite athletes, even if they are participating in different types of activity."

medical device" or "transform a mobile platform into a regulated medical device" and defining them as "mobile medical apps" subject to agency marketing approval.

"The use of mobile apps on smartphones and tablets is revolutionizing healthcare delivery," Dr. Jeffrey Shuren, director of the Center for Devices and Radiological Health, said at the time. "Our draft approach calls for oversight of only those mobile medical apps that present the greatest risk to patients when they don't work as intended."

The rigors of the regulatory process could well push more drug and device firms into the arms of developers like AgaMatrix, whose familiarity with the FDA's thinking on mobile medical apps was attractive to Sanofi.

"It's a learning experience for us, and that's one reason we're choosing partners that have experience in this space," says Sanofi's Whitaker, "so we can learn along with someone who is experienced in getting products like this—solutions and services—to market."

For Withings, a French company founded by two telcom execs that manufactures an iPod-integrated blood pressure monitor and Wi-Fi body scale, getting FDA approval was an eye-opener.

"It's a barrier for a company that comes from the consumer market," says CEO Cédric Hutchings. "From A to Z it might be an 18-month process. These are regulated markets and it's normal, but it does take time, energy, resources and risk taking to go through this process."

For payers and providers, though, an FDA approval lends credibility to the few apps and i-devices that have gone through the process.

"Rigorous clinical support is one of the things that separates regulated medical apps from everything else in the app stores, which may be well designed but not based on science," says LifeScan's Shields.

Withings competitor iHealth, an mHealth subsidiary of Beijing-based Andon Health, was first to market with an iDevice-driven blood pressure monitor (the iHealth Blood Pressure Dock, for $99.95), which landed in Apple Stores (and pharmacy chains) in March 2011. As with Withings', it's considered a Class II medical device. The firm is now working on a scale, slated for a fourth-quarter launch, along with a glucometer that's currently going through FDA.

It's a traditional retail model, "The razor and the blade," says general manager Adam Lin, who adds, "It's a very reimbursable business." The Blood Pressure Dock has "in the six figures" of users, says Lin. The two-year-old firm's fleet-footed moves have won it some attention from drug companies.

"With this technology, the lifecycle is significantly faster," says Sanofi's Urbaniak. "So it's not about a 10- or 15-year process to develop a drug…From a software point of view, sometimes it's just a matter of making some quick adjustments, where it's not always easy to do that with a drug."

Sanofi has also reached out to the tech world through its Data Design Diabetes challenge, now in its second year (Janssen has a similar program, though not diabetes-focused).

"It exposed us to a whole new world of service developers and talent—external partners that we typically did not interact with at any scale. And we did the whole process in just months, so the speed at which we got these high-quality ideas was fantastic. It would have taken years to get a comparable level of key partners to work with." ■