



**5 breakthroughs at the intersection of devices and diagnostics** that promise to make healthcare more effective and accessible. **Matthew Arnold** reports

# A VIEW TO A PILL

**E**ven eight years after its *Today Show* cameo, Given Imaging's PillCam sounds like something out of a Bond film. The Israeli company is about to launch the third generation of its capsule-sized camera, made famous by Katie Couric, who shared PillCam footage of her esophagus with viewers back in 2005.

PillCam moves painlessly through the gastrointestinal tract transmitting images to a recording device worn on the abdomen. Those devices are then compiled into video to be read by the physician and, at the physician's discretion, shared with the patient. It's one of a burgeoning field of innovative technologies that sit at the intersection of devices and diagnostics, carrying the promise of making diagnosing disease more effective and accessible.

PillCam SB3—which, pending 510(k) FDA clearance, will launch in the US—will offer a sharper image and adaptive frame rate technology that compensates for its rate of movement, so that it snaps more pictures as it moves faster. Given also redesigned the optics and imager for a 30% improvement in resolution, and tweaked the software to make it 40% more efficient in video compilation. All that is designed to help clinicians better spot Crohn's disease-related lesions that would go undetected by upper or lower endoscopy.

"It's efficient, patient-friendly and clinically proven to provide visualization of the small bowel in its natural state," says Given VP global marketing Jonathan Huber. "There's minimal preparation required, the procedure is non-invasive and does not require sedation."

What's more, says Huber, it reaches areas of the small bowel that are inaccessible to other direct-imaging modalities like upper and lower endoscopy, and does not expose the patient to radiation as do indirect imaging technologies like CT Enterography (CTE).

The device also offers an excellent platform for patient education—one gastroenterologist told Given he uses the videos to talk to patients about the condition of their small bowel mucosa, and that this helps promote compliance.

So perhaps it's not surprising that the company is now prepping its first-ever consumer

PHOTO: BILL BERNSTEIN WITH IMAGE FROM THINKSTOCK

campaign, a digital-focused effort aimed at building awareness of the device's utility in Crohn's. It's anchored in a website, PillCam-Crohns.com.

"The hurdles we face for adoption of our product for detection and managing patients with Crohn's disease are primarily rooted in awareness of the device's utility for this disease," says Huber. "The public awareness that was built through the Katie Couric procedure was great, but in our view we've got to start now moving forward and building more awareness relative to Crohn's disease. By informing more patients about the procedure, we're optimistic that patients will discuss this option with their physicians."

On the professional side, Given boasts a field force of nearly 100 calling on specialist and community GI docs. The company trains doctors and staff—reading PillCam video typically requires at least 25 cases—and offers educational webinars and CME opportunities to keep them on their toes while sponsoring CapsuleEndoscopy.org.

PillCamCrohns.com guides visitors through a journey meant to

### DOC IN A BOX

What if you could schedule a doctor appointment on a few minutes' notice at the supermarket? Columbus, Ohio, startup HealthSpot plans to bring telemedicine to the masses with souped-up kiosks that can serve as remote exam rooms, equipment and all.

The company has designed two versions—one a fully-enclosed, 40-square-foot number resembling a Sanisette, complete with medical attendant, the other a standup version dubbed the RetroFit. You make an appointment, with your doctor or any available doctor, and fill out a Virtual Clipboard, just as you would the pen-and-paper version at a bricks-and-mortar doctor's office. In the full-sized HealthSpot Station, the patient is seated before a video screen. Little doors in the walls conceal medical equipment—a Bluetooth-equipped stethoscope, a dermascope and an otoscope. The physician can pop them open with the press of a button, and the medical assistant will help the patient use them. Vitals are displayed onscreen for the patient to see and sent to the provider. When the appointment is over, the medical



mirror the uncertainty many patients feel just after diagnosis. The site opens with the headline "When it comes to Crohn's disease, does it feel like you're in the dark?" Visitors progress through a series of screens that gradually get lighter, culminating in the headline: "Shed some light on your Crohn's." Along the way, viewers learn that 62% of Crohn's patients in a recent survey had changed medications following PillCam SB evals as a result of the findings.

In concept testing, they found that "these people had had colonoscopies, endoscopies, MRIs, CT scans, and some of them are still experiencing symptoms," says Jeff MacFarland of Intouch Solutions, Given's agency partner on the consumer campaign. "So they're really in the dark when it comes to their disease, and PillCam sheds light on Crohn's in the small bowel. It's like this fantastic voyage or inner space journey, and we knew we had to recreate that on the website."

assistant cleans the equipment and sanitizes the kiosk. If the doctor writes a prescription, it's beamed over to the pharmacy electronically.

"Our mission is to create the highest-quality, lowest-overhead, lowest-cost healthcare appointment in America," says HealthSpot's Lisa Maughan, VP of marketing. "It's another access point that can help get people to the doctor." HealthSpot envisions a distribution scheme similar to Redbox, whose scarlet kiosks dispense movie and game rentals at shopping centers throughout suburbia. The firm is also in talks with health systems, for which the kiosks could serve as urgent care overflow and to divert non-essential traffic from the ER.

For developer Higi, which has built an app that tracks health behavior and gives consumers a RealAge-esque score, kiosks provide a means of acquiring new users.

"It's very challenging to get consumers to engage in health and wellness," says CEO Khan Siddiqui, MD. "We asked: Can we find

something that people are already using and connect to that? Those old analogue blood-pressure kiosks that you see in grocery stores and pharmacies are used by 70 million unique individuals annually and deliver around 500 million vital signs. And we thought: Hey, can we get into that loop and engage patients there?”

The Chicago-based firm has rolled out 1,000 kiosks since September and has seen 1.8 million users, who are served “very targeted” ads as they fill out a form to determine their score.

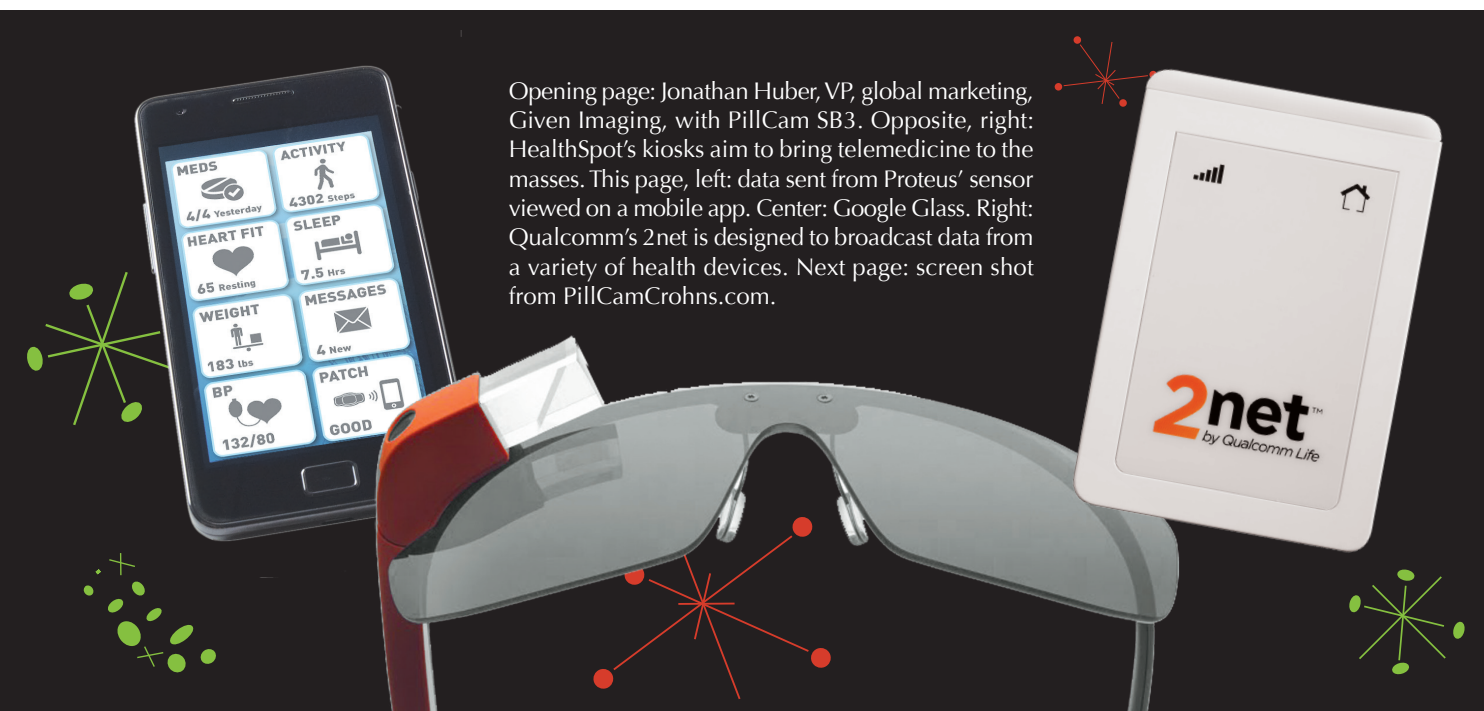
Users can input vitals data from Withings devices, and Higi is talking to other consumer health trackers such as Fitbit. A social element, whereby users compete with friends and family for health achievements, will help to reinforce healthy behaviors. Health economist Jane Sarasohn-Kahn of THINK-Health says kiosks like HealthSpot, Higi and SoloHealth’s “represent the extension of primary care, especially for prevention and self-tracking. It’s a wrinkle on the retail clinic encounter, with a little Star Trek Hologram thrown in.”

reads their devices and broadcasts the data to a secure system from which it can be accessed by healthcare professionals. Alternately, the 2net platform can be accessed by mobile phones and apps, medical devices with an embedded cellular component or by partner service platforms using application programming interfaces. Qualcomm Life has already signed up 250 customers for the platform.

“This basically enables device manufacturers and health service providers to get their medical devices connected and get the data moving without having to be in the wireless business,” says Valencia.

Because Qualcomm Life is primarily a business-to-business company, they needed to look outside to get that data to consumers in an actionable format. Through a partnership with WebMD, Qualcomm hopes to leverage the portal’s presence in consumer healthcare to give patients a front end through which to read that data—along with a “storefront” displaying available devices.

“While it’s out there with early adopters, you don’t have broad awareness, and for a lot of people in the mainstream, this would



Opening page: Jonathan Huber, VP, global marketing, Given Imaging, with PillCam SB3. Opposite, right: HealthSpot’s kiosks aim to bring telemedicine to the masses. This page, left: data sent from Proteus’ sensor viewed on a mobile app. Center: Google Glass. Right: Qualcomm’s 2net is designed to broadcast data from a variety of health devices. Next page: screen shot from PillCamCrohns.com.

## DATA LIBERATOR

A couple years back, wireless giant Qualcomm launched Qualcomm Life to fish for opportunities in healthcare. They found a field of devices designed to monitor the health of elderly or recently-discharged patients on a continuous basis. However, manufacturers and providers, says general manager Rick Valencia, “needed to move to wireless, but they also needed something that would actually work in the home.”

“We have plenty of tools,” says Sarasohn-Kahn. “Now it’s how do we streamline their use and get them to be enchanting to the user? The answer is ease of use and convenience and all that good stuff that gets overlooked by tech developers.”

Enter Qualcomm’s 2net, an FDA Class I-listed, device-agnostic cloud-based platform that facilitates wireless communication of biometric data. Patients can plug in a 2net Hub, a nightlight-sized device that comes bundled with their devices and, once it boots up, it

still be kind of a science project,” says WebMD Chief Technology Officer Bill Pence. “The time is now to bring it to a mass audience.”

To that end, WebMD is redesigning its flagship app (which, together with the company’s other consumer apps, has notched 172 million downloads) to give consumers an “aggregated dashboard” packaging their data and giving them condition-specific device recommendations.

“If you’re a diabetic or you’re at risk of developing diabetes, we can present to you, in the context of your access to WebMD, this emerging category of technology where you could pull all that data into this app that’s in the field,” says Pence. “We think there’s an opportunity to do not just data aggregation but also to make it meaningful.”

WebMD’s display will bundle data from fitness trackers as well as more disease-oriented devices. “While we’re not targeting fitness by any means, because we think that area is well served, fitness devices are really general purpose activity monitors, and a lot of conditions

like diabetes have a strong component of upping your physical activity, your calorie burn,” says Pence.

Qualcomm also acquired Healthy Circles, a “care orchestration engine” designed for hospitals and providers to set up coordinated care between patients, providers, caregivers and institutions.

“Getting consumer awareness is critically important,” says Valencia. “WebMD’s brand presence and size enables a new awareness of the availability of these solutions but also easier access to getting the solutions at scale.”

### THE SENSOR YOU SWALLOW

As wearable wellness and fitness trackers have exploded, with dozens now on offer, a parallel burst of activity has been taking place, if more quietly, on the medical side as device makers turn to implantable gadgets that provide a continuous stream of biometric data.

One such device is Proteus Digital Health’s ingestible sensor, which can be placed in a pill. Once it reaches the stomach, the sensor issues a signal, broadcasting the timing of ingestion to a patch worn on the skin, which also tracks heart rate, body position and activity. The patch passes that data on to a mobile phone app, through which it can be accessed, with the patient’s consent, providing a foolproof means of measuring compliance and knowing when to remind patients to take their medicines.

“There’s a broader strategy around that, which is about creating behavioral diagnostic tools that link an individual’s decisions to take their medicines and how they take those medicines to how their bodies respond,” says Proteus Chief Product Officer David O’Reilly. “This emerging space of wearable sensors and other technologies is turning our bodies into data feeds... This is personalized medicine from a behavioral standpoint—what were the day-to-day decisions of an individual around medication, diet, rest patterns, physical activity, that influence care and outcomes?”

And such sensors could have huge implications for post-market monitoring of drugs and biologics.

“We have pharmaceutical products which are validated and approved in clinical trials which are relatively small, which are highly controlled, and which have people who, based on all the exclusion criteria, really don’t look like you or anyone who has that actual disorder,” says O’Reilly, “and then they get approved and they get sent out into the real world, where we are very heterogeneous as a population and make very different decisions than a clinical trial subject. So having sensor-based systems that can gather data on a 24/7 basis that embraces that variability and tries to understand how meds are used in the real world and improve on them, that’s a major opportunity.”

“There is great value beyond diagnosis for chronic conditions where [sensors] are needed to closely monitor a variety of biological inputs,” says digi-health consultant Raj Amin. “This can redefine medicine in ways through analysis of large data sets against actual outcomes. But there’s also a Big Brother, ‘cyber-

human’ effect that will need to be managed to get these deployed to massive populations. An exciting area of technology for sure when combined with applications that make sense of this data for personalized services and large-scale population health problem solving.”

But rendering that data useable is where it gets tricky, says Amin, who is working with Mana Health, whose data-visualization project is a finalist in a New York State patient portal contest.

“Even state governments have realized that if you don’t get patients to start engaging with the data, then they don’t really understand what’s going on,” says Amin. “Once they do... better behaviors start.”

### AUGMENTED-REALITY GOGGLES

Wearable sensors are already transforming wellness, but Google’s Project Glass promises to deliver something much more disruptive.

The augmented reality-enabling goggles, expected to be on sale next year, offer “the clearest view of what wearable computing will do for us,” says Larry Mickelberg of Havas Health. “There’s going to be this smart layer that supplants your physical view of the world.”

Daniel Kraft, MD, whose FutureMed program at Singularity University hosted Project Glass founder Babak Parviz, sees augmented reality tech revolutionizing the physician’s job. “It will unglue us from being stuck in our EMR or looking at our phone or tablet. It’ll help liberate data and make physicians smarter.

“If I’m an orthopedic surgeon and I’m looking at the shoulder of the patient that’s had a fracture, I can layer over that the CT or the X-Ray data, so I can integrate my intervention, the diagnostic component and the therapeutic. Plus, when you add in elements like IBM’s Watson, I might say ‘Glass, what’s the best antibiotic choice for Lyme disease for this patient who’s pregnant and allergic to penicillin.’”

IBM’s Watson is an artificial intelligence system designed to answer questions posed in natural language. Wellpoint is trying it out as a utilization-management tool in lung cancer cases at MSKCC.

Glass, says Mickelberg, “makes this notion of remote medicine more possible. A surgeon could be performing a delicate surgery and potentially on-screen have another KOL who’s viewing the same surgery and giving instruction. A pharmacist could have a database of medication and quickly check the pill being dispensed against an image to make sure they’ve got the right pill. Hospital systems are getting far more integrated, and if you add Google Glass to that, a healthcare professional could instantly have all of the patient’s vitals right there.”

On the consumer side, says Dr. Kraft, Glass “changes how you’re connected to others. Let’s say you’re connected to a family member who has a chronic disease. It has some powerful implications for how we interact.”

“We’re a ways out from any large-scale implementation of any of these things,” says Mickelberg, “but smart companies that had tabled thinking about augmented reality because there wasn’t really a suitable device or market might do well to restart that process because this is a channel to do that.” ■

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But the actual number of people with Crohn's is probably more like **1,000,000**

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And 75% of Crohn's patients have lesions in their small bowel.

And capsule endoscopy is the most patient-friendly method to obtain complete direct visualization of the small bowel.

This is where your colonoscopy ends.

When it comes to Crohn's, you might feel like you're in the dark.

Shed some light on your Crohn's.