THE WEARABLES PHENOMENON:

DIGITAL DISRUPTION IN HEALTHCARE

Dr. Erin Grossi | Chief Economist

Several traditional markets collided to initiate the wearables phenomenon a few decades ago.

It set off a movement that has only continued to expand opportunities for market relevance of wearable technology. Unsurprisingly, the retail fashion industry was an early pioneer of wearables, with accessories like the calculator watch of the 1980s serving as natural conduits to consumers already inclined to wear items for fashion value, providing them opportunities to accrue new digital benefits as well. Today, the Apple Watch is one of the most prominent examples of technology being introduced primarily through the fashion vehicle, and there is a whole series of "wearable art" or "fashtech" that is emerging, with overlap into 3D printing and LED lighting for displays as well. Fashion was one of the two largest platforms for wearables that were visible at the Consumer Electronics Show (CES) this year, and related fashion applications continue to expand and evolve in the market. The other major platform for wearables is functional technology, with the fitness industry and consumers who value health & wellness solutions being one of the major targets of these early types of technology. Wristbands like Fitbit or Under Armour apparel

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are increasingly capable of measuring and reporting data around movement, step-count, sleep quality, heart-rate, and many are promising to capture more on nutrition and even mood in the near future to help individual consumers keep track of what is happening with their bodies and better maintain and care for their bodies in the future, among other uses.

The two primary wearables platforms (fashion and heath & wellness) make up the vast majority of wearable technology available in the market today. Technology Research organization, Gartner, indicates this market will reach 274.6 million units in 2016, an 18.4% jump from the 232 million units sold in 2015. They estimate the market will drive $28.7 billion in revenue in 2016. Of that total, $11.5 billion will come from the fashion platform, which includes smart watches, and it is expected to maintain the greatest revenue potential among all wearables through 2019. Head mounted displays, blue-tooth headsets and smart garments are also on the rise and expected to grow significantly over the next five years as the two original platform markets expand and mature.
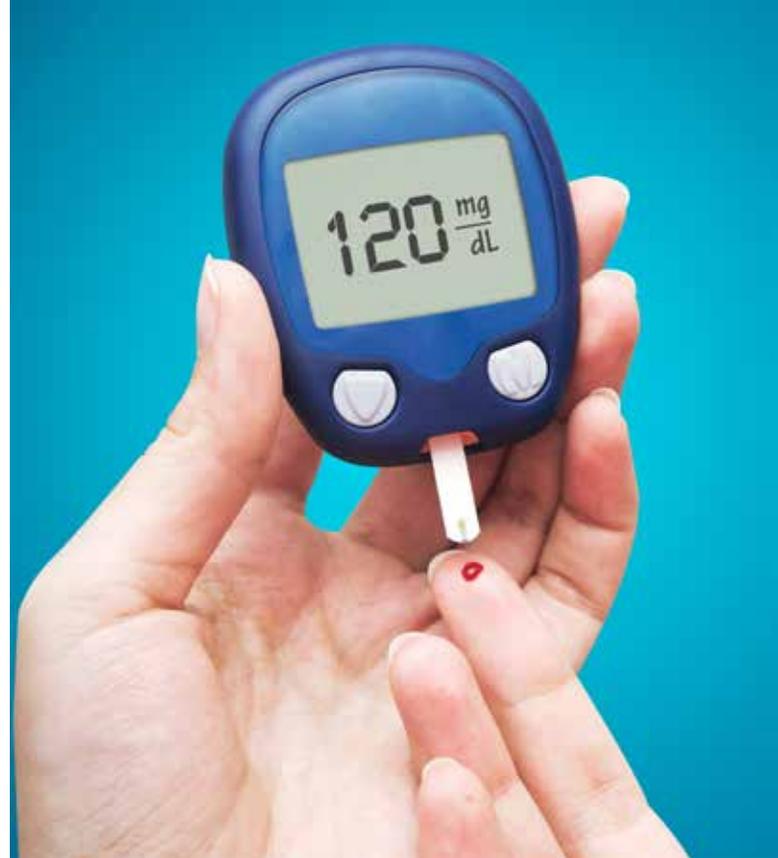
UL, like many other engineering services and technology-oriented companies, quickly spotted the market potential for wearable technology being marketed to consumers and we responded by putting together a comprehensive portfolio of services for

manufacturers that can support their efforts to bring safe, quality devices to market and also avoid some of the more costly mistakes manufacturers are at risk of making, particularly in new and emerging technology spaces. Helping solve challenges with biocompatibility, microbial/virological issues, extending the overall shelf-life of devices and helping manage their transport safely, among other non-clinical concerns, were some of the initial services UL offered customers in the wearables space.

MOVING BEYOND FITNESS & FASHION TO THE DOMAIN OF MEDICAL DEVICES

As wearable technology evolves, however, new market challenges and opportunities are emerging in ways that continue to shape UL's approach to developing standards and gauging conformance to those safety and performance measures. The single biggest market driver of our future thinking and service-development approach is the increasing digital disruption wearables are now facilitating within the medical devices sector and, in fact, the entire healthcare vertical.

It did not take clever individuals with technology and/or medical backgrounds a long time to figure out that the ability of wearables devices to not only track and report basic biological activity, but also to track important physiological data and provide meaningful health and wellness diagnostics and better linkages to healthcare providers, could all be hugely valuable to consumers, providers, and other participants in the healthcare ecosystem. Today, there are established technology giants (IBM, Samsung, Apple, and Google to name a few), as well as a crop of start-up companies, that are working on all segments of the healthcare value chain for wearable technology, with some, for instance, developing sensors that can either mimic or be embedded in human skin, as well as sensors that can be implanted or ingested, and others focused more on the algorithms that can interoperate sensors, categorize and interpret data from a range of sources, and provide an equally

vast amount of meaningful measurements and alerts. In a very short amount of time, the technology is shifting beyond a focus on the wearable devices themselves, and is more firmly situated around actually solving pain-points for consumers and healthcare providers of all kinds. That's all happening because of the power of Moore's Law, which describes the incredible capacity for technology to accelerate and advance as a function of time.

As wearable devices more frequently traverse the traditional boundaries between consumer products and medical devices, UL has similarly adapted its orientation to the market by providing increasing types of performance evaluations and cybersecurity reviews as well. Fitbit is one company currently experiencing

the increasing demands for precision that inevitably arise with the wearables' increasing proximity to the traditional healthcare industry. The company is currently facing a class-action lawsuit alleging that its heart rate monitoring technology is inaccurate, which could be dangerous for some consumers, heart patients in particular. Recognizing the likely increase in performance validation that will continue to be demanded by the market as wearables claim to monitor and provide feedback and alerts for increasingly sophisticated physiological data, Anura Fernando, UL Principle Engineer for Medical Software and Systems Operability, said UL began offering performance verifications to wearables manufacturers that were calibrated to medical-grade tests. "There are a lot of opportunities to apply medical

standards to wearables measuring the same physiological parameters devices do today. The science of these performance evaluations is also evolving. With increasing prevalence of head-worn technologies, for example, we are finding it increasingly important to study the physiological impacts of multi-spectrum radiation, which nobody has done yet," according to Fernando.

DIGITAL DISRUPTION IN HEALTHCARE

The increasing performance of wearables and their abilities to perform functions that were once the sole domain of prescribed medical devices is something that makes the existing medical device industry increasingly apprehensive and concerned. With the U.S. Food and Drug Administration deciding to take a hands-off approach to regulating wearable technology, issuing informal guidance to industry rather than even minimal regulations for the devices, the doors have been thrown open to digital technologies of all kinds to market directly to consumers in ways that have already been disruptive to device makers. Star Cunningham, Founder and CEO of 4D Healthware, LLC, a start-up company that aggregates information from hundreds of wearables and other devices to create insights for healthcare providers about people with

multiple chronic conditions, explained that while some device manufacturers are waking up to this phenomenon with wearables, others have been slow to adjust. "Consumers used to have limited options for products like glucometers, and the companies that made those devices were effectively operating as monopolies," says Cunningham. Today, she explains, consumers can find similar products on Amazon and other outlets that connect directly to their smart phones. According to Cunningham, "The paradigm shift happening in healthcare where patients are increasingly taking on out-of-pocket expenses to care for themselves has them in search of devices that offer them more control over their bodies and their related health information."

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> *- Gary Conkright*

Gary Conkright, Founder and CEO of another start-up company called physIQ, a cloud-based analytics platform that processes data and provides healthcare providers triage information for monitored patients through a variety of wearable devices, agrees that there is a monumental shift underway in the healthcare industry today that can no longer be ignored. "Healthcare and IT are converging" explains Conkright. "The days of having traditional healthcare providers and their vendors silo'd and working on their own, slow innovation track are over. The IT industry with its orientation to iterate on products, fail fast and learn from mistakes in real-time are converging on traditional healthcare turf. The result is that traditional healthcare will need to innovate faster, with an eye toward performance outcomes, and IT will have to be more disciplined and process-driven in this environment, given the high-stakes."

The digital disruption taking place in healthcare today, aptly described by some of the wearables entrepreneurs, comes at a time when the Affordable Care Act legislation, signed into law in 2010, is catalyzing even larger systemic shifts in the healthcare industry at large, democratizing healthcare in many ways and putting traditional ecosystem players like insurers in fierce competition with new market entrants that had not been a major factor in the past, including but not limited to pharmacies like Walgreen's. The result is insurers, particularly those that are not also providers, are increasingly put in the position of having to radically re-think their entire business models and approaches. As a result, insurers are some of the most attuned stakeholders in the wearables phenomenon that is occurring today, with many of them investing in the technology, as one of several mega-trends capable of shaping the future orientation of the industry.

IT'S ALL ABOUT THE DATA

Eric Steager, Managing Director of the Strategic Innovation Portfolio, which evaluates strategic investments in early-stage healthcare technology including wearables, among other solutions, for Independence Blue Cross,

says that the insurer is gauging the value of wearable technology primarily on the basis of the associated data and potential insights. "Questions I'm always focused on are who is using the data, how is it being used, why is it being used, and what is typically being done with the data," said Steager. He says perhaps the most exciting element in the movement is passive monitoring devices that can make reliable health-related predictions and issue alerts. "If predictive analytics can be leveraged to tell you that you will be diagnosed with a disease in 18 months, it could be very valuable for the betterment of our members' health. Further, imagine that in the future if, in best case, wearables could provide 48 hours' notice that you are going to have a heart-attack." Still, Steager says, "there remain challenges because

for all these potential advance warnings and associated benefits, how can we as an insurer really use this data? Who is in the best position to act on it? The individual, the physician, the insurer? Also, how does one account for liability associated with remote care?"

These are just some of the key questions being asked today around the usability of medical data which most consider the crown jewel of the wearable tech movement. Capturing quality data, organizing it, interpreting it and helping consumers to avoid health problems while also helping providers to quickly and effectively diagnose problems and avoid catastrophic outcomes is where the critical value really lies, which is why so many in the industry are increasingly focused on the data-

side of wearables equation. The most advanced operations in this regard are working to apply techniques from Artificial Intelligence, including predictive analysis and machine learning techniques, to create proprietary algorithms that the consumers and providers can rely upon to make sound and effective medical judgments in real-time.

The pain-points to solve are plentiful and challenging, meanwhile the potential savings to individuals and the healthcare system at large that can be realized through prevention, more effective management of existing health problems, not to mention all the time saved by health practitioners, in particular, that could be meaningfully driven into new avenues of scientific exploration, research and development of new drugs and devices, etc. are extraordinary ambitions. All of this, combined with the fact that the healthcare vertical is shifting to a value-based and performance-based orientation today, means that it continues to be a highly active time for major investments in wearable tech. It's one of the reasons that the International Monetary Fund has estimated the global healthcare sector as a whole is poised to grow more than 6% annually over the next decade, far out-pacing the growth of most individual countries in the sluggish global economy we have experienced since the Financial Crisis of 2008.

As the focus in the wearables shifts increasingly to honing the data itself, supported by
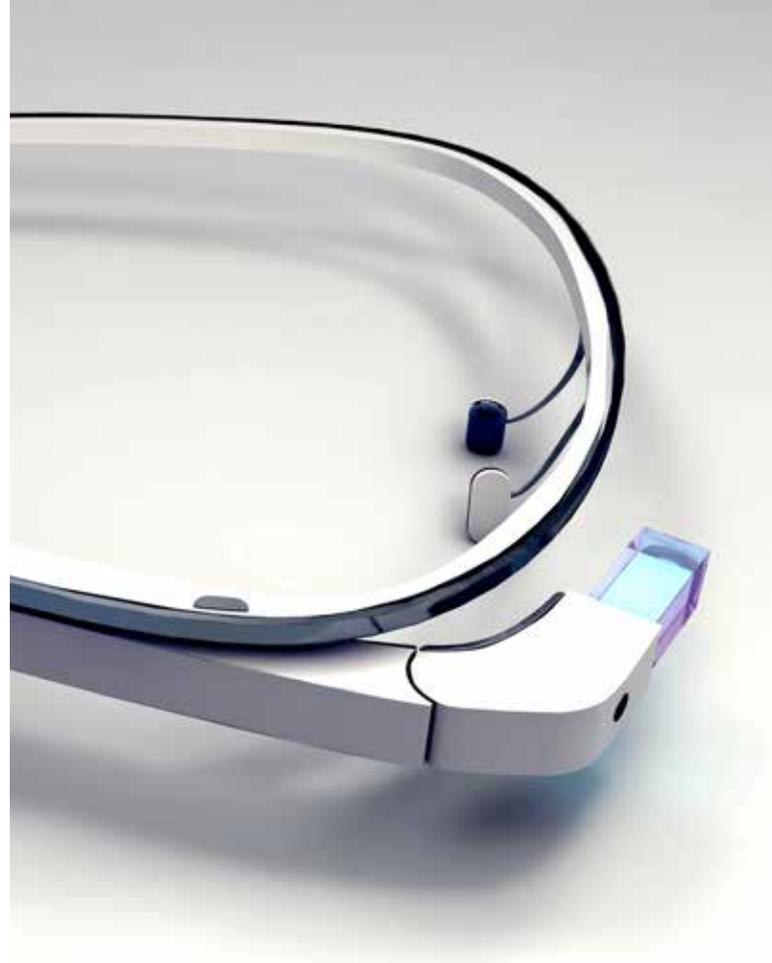
increasing data quality achieved, in part, by improving hardware performance over the years, UL is expecting a decisive shift over to the most pressing safety and security challenges as well. This is why we are at work now developing more sophisticated performance evaluations for wearables, to verify their abilities to increasingly perform in an accountable fashion like medical devices, as well as more comprehensive cybersecurity assurance programs that can help protect sensitive physiological and medical data in ways that will not harm consumers or the system as a whole. This becomes important as the more significant value-propositions achieved through cognitive computing entice additional consumers to use wearables
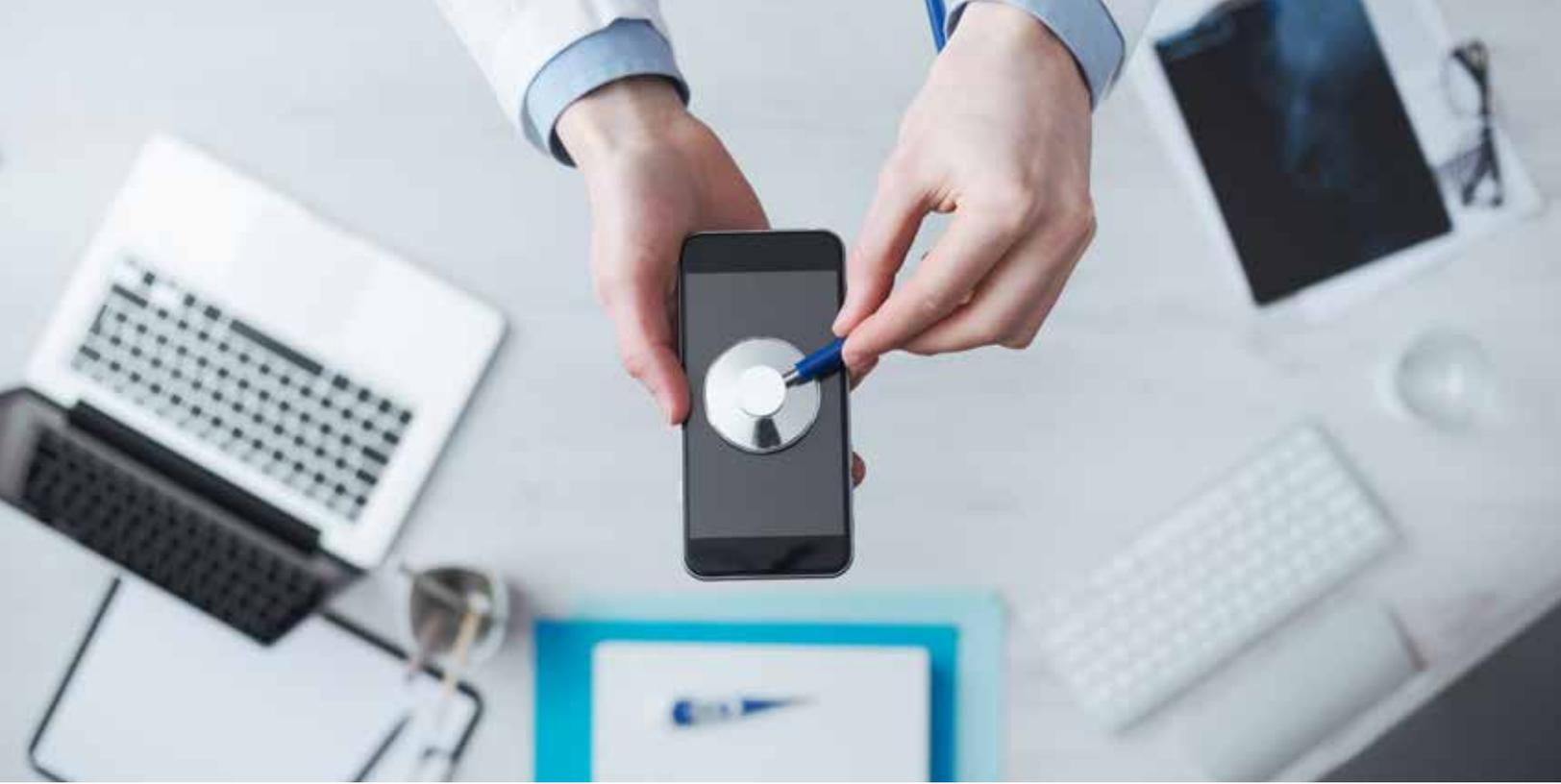
solutions and thus generate vast amounts of new data. As UL's Anura Fernando explains, "There are a lot of research blind-spots in cybersecurity today. Bringing the significant research problems into the structured environment of a nationally recognized testing laboratory, rather than leaving it in the hands of individual hackers, has become a global imperative."

In sum, UL continues to advance scientific knowledge, as well as a range of meaningful evaluations for wearables, as they increasingly blur the lines between consumer devices and medical-grade technologies. We perceive that as wearable hardware increasingly becomes smaller, perhaps nano-scale, and embedded

in humans and products, there will be ever-increasing safety and performance measures that will need to be developed and applied across the industry.

Meanwhile, the overall industry focus will increasingly shift upstream to the data itself, as the most valuable element of the wearables' movement, with needs to protect such high-value data only continuing to become more pressing.

By Dr. Erin Grossi, Chief Economist, UL LLC