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HEALTHCARE INNOVATION:

the big ideas shaping the future of pharma

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Introduction

The transformational changes taking place in healthcare are challenging for everyone, but for the pharma industry adaptability is rapidly becoming a critical component of success. It doesn't matter if the perspective is technological, scientific, economic or human, the world that has served pharma so well and for so long is fast becoming unrecognisable.

The nature of pharmaceuticals, however, brings a host of obstacles in the pathway of change. Its long production cycles, for example, tend to be served by separate functions that convene at particular milestones within each product-development journey. This partly explains why industry's most visible adaptation to a value-driven world has been to concentrate on specialist drugs; the prices of which only exacerbate the cost pressures that are forcing fundamental rethinks in healthcare delivery.

But unsustainable economics are just one aspect of the current revolution taking place in healthcare. The real changes are made possible by technology that enables patients to be central to decision making, as well as the outcomes they experience from treatment to be what determines reimbursement, rather than the mere provision of services. These two factors have prompted a whole raft of new technologies that is notjust disrupting, but shattering, conventional understandings about medical authority and influence, about where patients should be treated, how they should be treated, even what it means to be well.

This new environment has come about via the convergence of several factors, not least of which is the ubiquitous use of smartphones. Alex Butler, joint managing director of digital consultancy The Earthworks, believes that this factor alone, by giving ordinary people instant access to both knowledge and each other, is responsible for the enormous cultural changes that are currently democratising medicine. When this new sense of empowerment is taken together with the ability to track outcomes and know how medicines perform in the real world, a whole new framework for healthcare begins to emerge.

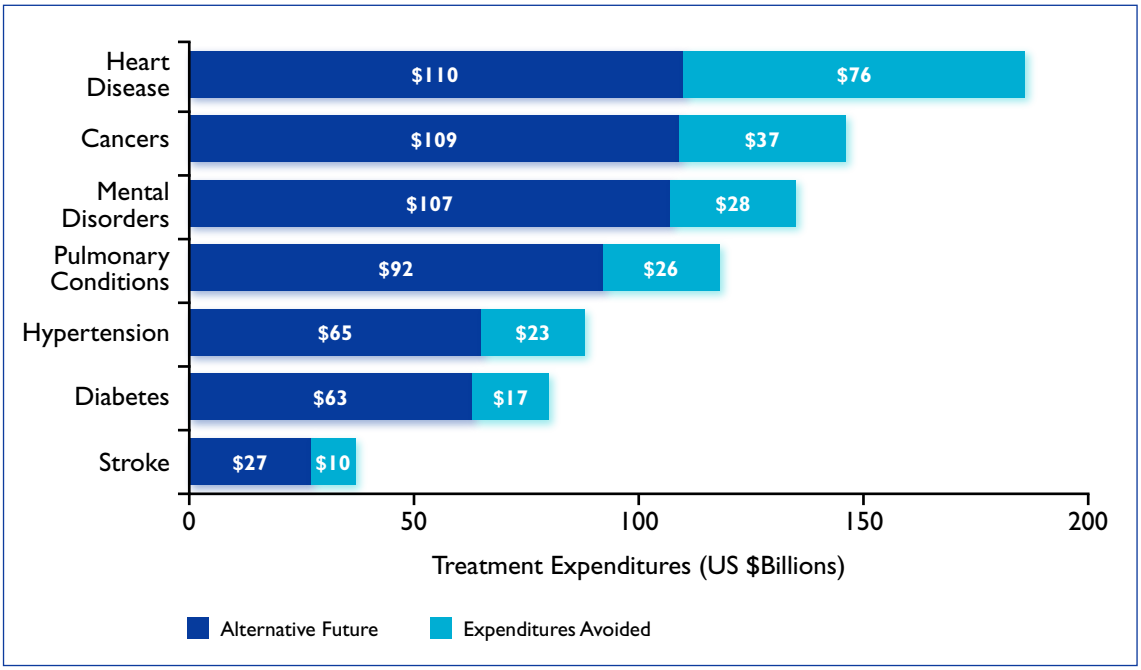
Part of this new framework is the recognition that, however much is spent on healthcare, unless individuals take responsibility for their wellbeing, the bill will only continue to grow. "The bottom-line is that no nation, no matter how wealthy, can provide innovative healthcare for its citizens unless it values wellness, prevention and disease management at least as much as it values acute care," said PhRMA president & CEO John Castellani at the 2013 Annual Meeting.[1]

Against this background, industry analysts are trying to predict the direction of travel for the pharma sector. PriceWaterhouseCoopers, for example, has identified seven major trends that companies must factor into their thinking. They are:

1 http://www.phrma.org/speeches/castellani-2013-annual-meeting-remarks

1. **The soaring cost of chronic disease.** Evidence to support more cost-effective spending when it comes to treating, managing and preventing disease is abundant. The US Partnership to Fight Chronic Disease, for example, has documented how more effective management in just seven common chronic diseases could avoid billions of dollars in direct, avoidable healthcare expenditures (see Figure 1). More specifically, by taking steps to better prevent and manage heart disease, the US could decrease healthcare costs by $76 billion by 2023. Greater longevity only adds to the healthcare burden and pharmaceutical companies will have to rely more on volume than cost because many countries won't be able to afford costly medicines.

Figure 1: Avoidable treatment expenditures in the US by 2023



Source: Milken Institute. An Unhealthy America: The Economic Burden of Chronic Disease -- Charting a New Course to Save Lives and Increase Productivity and Economic Growth.[2]

2. **Healthcare policy-makers and payers are increasingly mandating or influencing what doctors prescribe.** Treatment protocols are replacing individual prescribing decisions and pharma's target audience will become more consolidated and powerful, significantly changing the sales and marketing model employed by pharma.
3. **Pay for performance is in the ascendancy.** The measurement of economic as well as clinical outcomes will determine whether a medicine is used or not. The collection and interpretation of real world data (RWD) will become the norm for all interventions.

2 Reproduced at: http://almanac.fightchronicdisease.org/Chapters/ChapterFive.

4. **The boundaries between different forms of healthcare are blurring.** There will be a much more fluid relationship between primary and secondary care, between ancillary support, social services and the self-medication sector. Ultimately the patient will be increasingly at the centre of decision-making.
5. **The markets of the developing world, where medicines are likely to grow most rapidly, are highly varied.** Developing countries have very different clinical and economic characteristics, healthcare systems and attitudes to intellectual property. Accordingly, pharma will have to develop individual and flexible strategies.
6. **Many governments are beginning to focus on prevention rather than cure, enabling pharma to enter the world of health management.** To do this it will have to connect with patients and regain the trust of healthcare professionals and patients alike.
7. **Regulators are becoming more risk-averse.** This, coupled with increasing focus on more niche conditions, means the pharmaceutical landscape is in an enormous state of flux.

On top of these significant transformational changes comes new competition from companies that range from the smallest start-ups to technology giants such as Apple, Google, Intel, Blackberry and Samsung. They join telecom industry players such as Qualcomm, AT&T and Orange that have worked in mobile health for years. And while these tech companies may not be producing drugs, they are transforming how healthcare is perceived, how it is delivered and how it is evaluated.

These factors are driving a paradigm shift in the pharma industry and transforming its business in several critical ways. These include a new emphasis on:

- Championing wellness, rather than just treating disease;
- Connecting with stakeholders in a digital world;
- Understanding how to work with big data as it enables money to follow real-world patient outcomes.

Championing wellness: Is pharma *ready* for the challenge?

The shift towards disease prevention as the starting point of disease management is arguably the most radical challenge to pharma's traditional product-centric perspective on healthcare. But prevention is stressed in legislation on both sides of the Atlantic[3] that directly incentivises activities that support a healthier lifestyle.

The main driver is the sheer cost of unhealthy lifestyles with smoking, physical inactivity, alcohol and poor diet being the largest culprits. According to an independent paper[4] commissioned by the UK's Department of Health, these 'top four' are responsible for 42 percent of deaths from leading causes, approximately 31 percent of all disability-adjusted life years and around £9.4 billion in annual direct costs to the NHS.

3 For example, the 2012 Health and Social Care Act (HSCA) in NHS England and the 2010 Patient Protection and Affordable Care Act in the US.

4 (February 2010). Enabling Effective Delivery of Health and Wellbeing: An independent report. Retrieved at: http://base-uk.org/sites/base-uk.org/files/[user-raw]/11-06/pc.pdf.

The picture is no better in the US. A report from Trust for America's Health, a non-profit health advocacy group, found that programmes encouraging physical activity, healthy eating and no smoking were a better investment than those concentrating primarily on treatment.[5] This found:

- Prevention saves money: an investment of $10 per person per year in programmes to increase physical activity, improve nutrition, and prevent tobacco use could save the country more than $16 billion in annual healthcare costs within five years.
- There is a substantial return-on-investment in prevention: For every $1 invested in community-based prevention, the return amounts to $5.60.

Chronic conditions are said to absorb around 70 percent of all healthcare costs. Obesity alone is said to be responsible for more than 75 percent of high blood pressure cases and 20 percent of cancers in women and 15 percent of cancers in men. Obese adults are also up to four times more likely to develop knee osteoarthritis than normal weight adults among a catalogue of other conditions.[6]

People who do not engage in enough physical activity, have poor nutrition, and/or are obese are at increased risk for many of the already saturated primary care markets in type 2 diabetes, high blood pressure, heart disease, stroke, kidney disease, some cancers, arthritis, and chronic obstructive pulmonary disease. These are also the conditions where sensor technology is most pervasive because they are widespread and involve biometrics that can easily be monitored via phone apps. And the ability to measure and assess one's own health is one of the key cognitive, emotional and environmental factors involved in behavioural change as shown in Figure 2.[7]

Figure 2: Factors influencing lifestyle-related health behaviours

Attitudes	People's views or judgements in relation to their health
Beliefs	People's opinions of their health
Motivation	The process that drives health behaviours
Intention	A plan of action intended to affect one's health
Volition	Making a conscious health-related choice
Planning	Forming specific health-related aims and objectives
Social support	Psychological and emotional assistance from friends and family
Self-monitoring	Ability to measure and assess one's own health
Social and material environment	Modification of influences in the environment that will benefit health

5 (October2008). Prevention for a Healthier America: Investments in Disease Prevention Yield Significant Savings, Stronger Communities. Retrieved at: http://www.preventioninstitute.org/component/jlibrary/article/id-75/127.html.

6 Prevention for a Healthier America: Investments in Disease Prevention Yield Significant Savings, Stronger Communities. Retrieved at: http://www.preventioninstitute.org/component/jlibrary/article/id-75/127.html.

7 Davies, N. Healthier Lifestyles: Behaviour change. Nursing Times. Retrieved at: http://www.nursingtimes.net/Journals/2012/03/30/a/m/d/110614Lifestyle.pdf.

Mobile apps to monitor personal biometrics and activity levels are now pervasive (more on this later) and massively encourage the consumer movement in healthcare by providing the patient with the practical means to move beyond being just a pathology to be treated and to assume greater control of their own destiny. The growth of the Quantified Self movement, defined as self-knowledge through self-tracking, and sites such as CureTogether, which encourage people to rate and share their outcomes from various treatments, are testament to this.

Designed to Move

Such technological initiatives are complemented by programmes to raise awareness of the importance of movement and of building activity into everyday tasks such as using the stairs rather than the lift or walking rather than taking the car. A classic example is Designed to Move, a physical activity action agenda headed by Lord Sebastian Coe, the force behind the 2012 London Olympics. He believes that this agenda was an important part of the Olympics legacy.

The skill, he says, is in bringing health, education, civil society and transport together under the slogan 'moving more, living more'. He also describes how the initiative is partnering with a wide range of organisations to make the tax system more activity-friendly by zero-rating gym equipment, for example, or by working with Royal Institute of British Architects (RIBA) to design buildings that encourage people to move more.

The initiative has also been driving home the unsustainable costs of not taking action. Figure 3 shows how the direct and indirect economic costs incurred in the US, the UK, Brazil, China, India and Russia are soaring. From actual figures in 2008 to projections for 2030, Designed to Move claims to be able to demonstrate a 453 percent increase in the direct costs of inactivity in China and 477 percent in India.

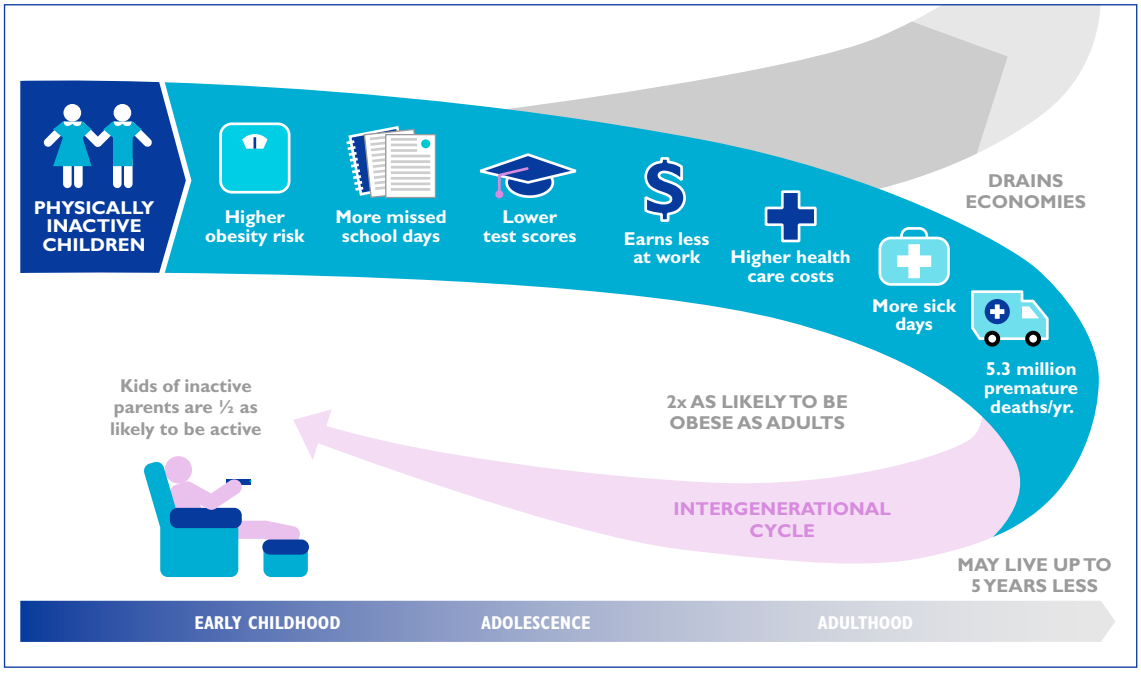
Figure 3: The economics of inactivity

Total Spend (US$) in 2008	2008 Direct costs (USA)	2008 Indirect costs (USA)	2030 Direct costs projection (USA)	% Increases in direct costs (USA) 2008-2030
USA  **$147B** or 2x the federal budget for the Department of Education (based on US$77.4B 2012 budget)	$90.1B	$56.5B	$191.7B	⬆113%
UK  **$33B** or Close to the National Health Service's annual efficiency target (based on £20B of annual efficiency savings over the next four years)	$16.1B	$16.7B	$26.0B	⬆61%
BRAZIL  **$11.8B** or Almost ½ of Brazil's educational budget for basic primary school (based on £20B of annual efficiency savings over the next four years)	$2.2B	$9.6B	$6.2B	⬆182%
GREATER CHINA*  *Data represents Mainland China only **$20B** or Almost 1/3 of China's total healthcare budget (based on 2011 planned investment of approx. US$63B)	$12.2B	$7.5B	$67.5B	⬆453%
INDIA  **$2B** or Equal to the total annual budget for secondary education (based on US$1.9B/year for 2007-2012)	$1.3B	$0.7B	$7.5B	⬆477%
RUSSIA  **$6.1B** or Close to the total health care cost of cardiovascular disease in 2009	$1.7B	$4.4B	$3.4B	⬆100%

Source: Designed to Move

There are also human costs. Figure 4 shows the effects of children becoming less physically active, something demonstrated by studies which show how physical activity among American kids drops by 75 percent between the ages of nine and 15 and by 50 percent among European children in the same age range. Research from mainland China, meanwhile, shows that 92 percent of kids get no physical activity outside of school.

Figure 4: The accumulative and damaging effects of physical inactivity in children



Source: Designed to Move

Pharma moves into wellness

The pharma industry is certainly within Lord Coe's sights. "Healthcare has to be about prevention," he says, citing the value of innovative solutions such as gyms designed to focus on stroke victims and stressing how illness involves much more than "just a technological answer to a pathology".

Pharma companies are starting to respond to these trends by building up their wellness credentials. Most of the larger companies, particularly those with significant consumer health divisions, now have initiatives on their websites to encourage healthy living. For example:

- Pfizer's 'Get Healthy Stay Healthy' programme is designed to connect people with reliable, easy-to-understand and practical information to help them take a more active role in their health.
- Novo Nordisk's 'Cities Changing Diabetes' programme is intended to fight the rise of diabetes in big cities across the world. It was launched in Mexico City in March 2014 with Copenhagen joining in August and roll-out extended to other cities in North America and Asia expected soon.
- Merck Consumer Care, the consumer products division of Merck, has launched the Active Family Project, a US health and wellness initiative to reach women who manage the well-being of their families and themselves.

- Eli Lilly's 'Lilly for Better Health' website encourages people to make healthier choices, understand their risks for certain diseases, and manage a health condition.
- Making More Health (MMH) is a long-term initiative from Boehringer Ingelheim to identify new and better ways of improving health globally. Since MMH started in 2010, a number of MMH initiatives have been launched by sourcing social innovation to provide more health in the future.
- Janssen's Care4Today Mobile Adherence programme is a digital platform that consumers can access on mobile and desktops to track their health and prescriptions.

Whether such moves, and these are only examples, can expand sufficiently to withstand the inroads into healthcare from the technology giants depends on several unknowns, not least of which is how quickly the healthcare revolution is gathering pace.

Digital pharma for a digital world

Digital professional Alex Butler also explains why he believes the pace of change is accelerating beyond most people's imagination. First, he outlines the basic elements of what he says is a perfect storm for change and one being led by people in the most democratic revolution in history. Ordinary people have, for the first time;

- Access to information in the internet and encyclopaedic sites such as Wikipedia;
- Access to each other in social media and the ubiquitous use of mobile phones;
- Access to technology in the some 27,500 consumer health and fitness apps now available. These can diagnose disease, facilitate participation in clinical trials, monitor various biometrics, obviate the need for several common medicines, and much, much more.

"It is no longer a question of whether pharma should be involved in social media," he says, moving the discussion swiftly on to the extent to which they should also be involved in wellness rather than illness.

Health, he continues, is a booming business for the largest companies on the planet. Already, according to a 2013 study by Kantar Media, 25 percent of smartphone owners and 22 percent of tablet owners use their devices to track their health, diet or exercise.[8] Companies such as Jawbone, Withings, Pebble and Fitbit have produced wearable technology that integrates with mobile apps, enabling more health and fitness data to be amassed. Moreover, evidence is mounting that monitoring, alone or coupled with coaching, improves health. Butler cites a study on a diabetes app which showed 57 percent of people recorded health benefits with no changes to their medication.

Home monitoring

Sensor technology does more than simply enabling people to see how their behaviour impacts their health. It also hastens change in the doctor-patient relationship by relaying vital information in real time from patients to their healthcare professionals. Sensors are a highly effective way of helping evidence-based decisions and are gaining in sophistication by measuring multiple metrics in one device, by linking to other devices, by becoming less obtrusive to minimise conscious interference and, importantly, by relaying the data to the medical record with alerts for healthcare professionals or carers if something is awry.

8 The Earthworks. Retrieved at: http://the-earthworks.com/blog/2014/could-today-be-the-most-important-announcement-for-digital-health-ever.aspx.

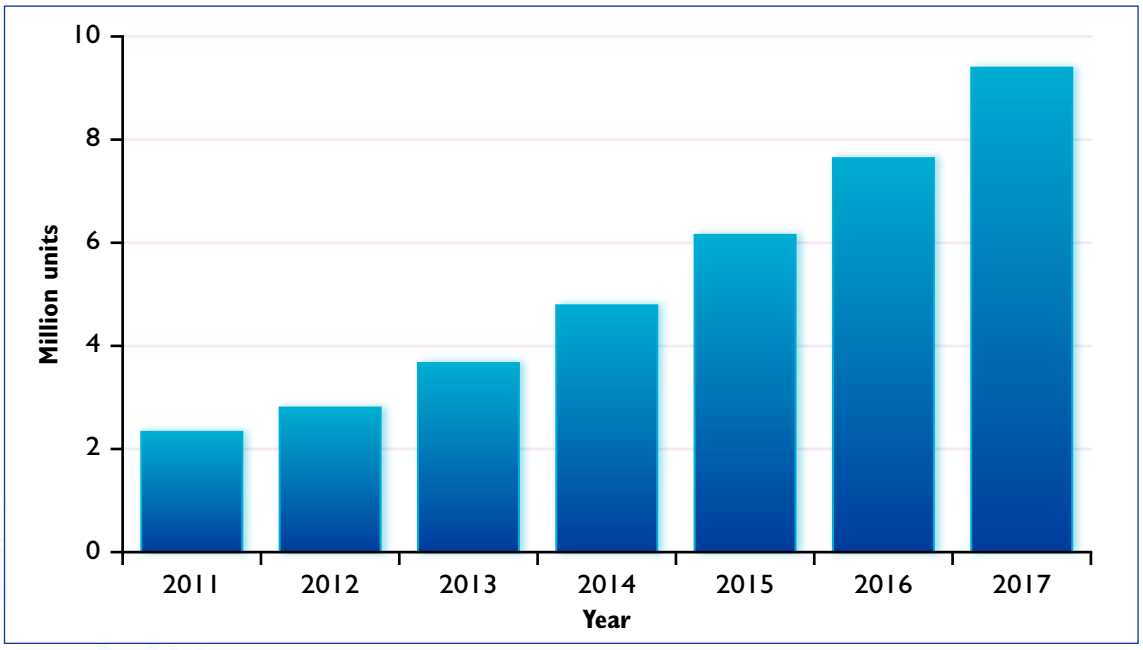
Now as small as a grain of sand, they are being deployed in healthcare in a variety of ways, including:

- Blood-sampling sensors, such as glucose meters
- Tissue-embedded sensors, such as pacemakers and defibrillators
- Ingestibles embedded in pills that dissolve
- Epidermal sensors, such as patches and digital tattoos
- Wearables embedded in clothing or accessories such as glasses
- External sensors, such as blood-pressure cuffs and pulse oximeters

There are also nanosensors in development that can live in the bloodstream and send messages to mobile phones when triggered by signs of an infection or impending heart attack. "Armies of tiny robots with legs, propellers, cameras and wireless guidance systems are being developed to diagnose diseases, administer drugs in a targeted manner and even perform surgery," reports a recent syndicated article in the *Washington Post*.[9]

Swedish consultancy Berg Insight estimates that more than 200 million people in the US and EU suffer from a disease where home monitoring can become a treatment option.[10] Excluding personal monitoring devices, it predicts that the number of patients using home monitoring systems with integrated connectivity will rise from 2.8 million worldwide at the end of 2012 to 9.4 million by 2017, as illustrated in figure 5.

Figure 5: Connected home medical monitoring devices worldwide, million units (2011-2017)



Source: Berg Insight[11]

9 'Smart pill' proponents see benefits, while sceptics worry about privacy. The Washington Post. Retrieved at: http://www.capecodonline.com/apps/pbcs.dll/article?AID=/20140524/NEWS11/140529813.

10 mHealth and Home Monitoring. Berg Insight. Retrieved at: http://www.berginsight.com/ReportPDF/ProductSheet/bi-mhealth-ps.pdf.

11 Ibid.

New competition

Technology giants such as Apple, Google and Samsung are entering the healthcare space by making digital health mainstream. The announcement of HealthKit at Apple's World Wide Developer Conference in June has particular pertinence. This has a huge data set that developers, including pharma companies, can tap into so that the apps they build can (with the permission of the user) offer more contextual advice to users on how to manage their medical conditions. It also has the advantage of leaving all the privacy problems associated with personal health data to Apple.

Apple is also rumoured to have its own health and fitness platform, Healthbook. According to Butler this is likely to be an app that enables the integration of a vast range of health and fitness data across Apple devices. Such data includes clinical information such as blood pressure, hydration, blood sugar, respiratory rate and oxygen saturation. And given that the company has also recently partnered with Mayo Clinic and electronic health records (EHR) vendor Epic Systems, which covers more than half of all US patients, some degree of threat is inevitable. The idea is that HealthKit will connect with healthcare institutions so they can intervene with patients whose readings fall out of normal range.

Google, meanwhile, announced Android Wear in March 2014. This is software that allows developers to create wearable technology that can interact with Android devices and has various healthcare applications. And Samsung recently revealed the outlines of a new health platform called SAMI into which a range of consumer health monitoring devices can report.

It is not possible to report on all the developments being talked about in this space. Apple's iWatch, Google Glass and IBM's Watson are further significant developments, the potential of which can only be surmised. As people around the world are persuaded to use them they naturally build up their health literacy levels to further trends in patient empowerment that are already in motion. Butler told the Big Ideas conference that Watson, an encyclopaedic diagnostic tool, can now be accessed via a consumer app, enabling patients to be better diagnosticians than most physicians.

The future for pharma in a digital world

Pharma is now seeking to adapt to the digital world in the face of radical upheavals in virtually all its business functions, including how it:

- Relates to stakeholders: Conventional message management has been upturned by many more stakeholders entering the fray, transforming channels of medical authority and influence.
- Conducts clinical trials and market research: Natural groupings of patients suffering similar conditions have transformed how pharma finds candidates for trials and it also learns what people, and not only prescribers, think of its products.
- Disseminates medical information: Open access publishing, coupled with new stakeholder groupings and more stringent transparency requirements, combine to democratise how the results of clinical trials are made public.

Lack of regulatory guidance has been cited as the major obstacle to change. But, after years of waiting, FDA pronouncements on how companies can and can't use social media have made it clear that the real problems stem not from a lack of guidance but from the inherent nature of ethical products: having to be fair and balanced in all communications, not having direct access to the consumer in several important markets and a track record of distrust among the public.

Ultimately, if pharma doesn't quickly adapt, it will be left as a commoditised pill provider.

Working with big data

Championing wellness and establishing the processes by which to work with social media are two immediate challenges facing pharma companies. An arguably greater challenge lies in understanding how to work with real-world data (RWD) as it enables money to follow patient outcomes. RWD is being embraced by healthcare systems around the world because it provides the means to know what works best outside the confines of a randomised controlled trial (RCT). And its importance is emphasised by Kingsley Manning, Chair of the UK's Health and Care Information Centre, who explains, "The use of data is likely to be as important in healthcare in the 21st Century as the pharmaceutical revolution was in the 20th."

Unravelling the hype

Pharma companies, like all other stakeholders, are on a steep learning curve to make sense of RWD and, in particular, to understand what can realistically be achieved now and in the future. This is not easy as RWD embraces all the human aspects of medicine that are deleted from RCTs. These include patient co-morbidities, lifestyle choices and the fact that patients seldom do what it says on the prescription label.

Additional obstacles include the fact that the datasets on which RWD decisions are based stem from insurance claims and electronic health records (EHRs) that are not always accurate, rarely cover everything pharma needs to know and don't readily interconnect with other data sources. Moreover, the data they reveal will relate to the medical protocols that are practised in the countries or healthcare systems in which they were created.

Health economics and outcomes research (HEOR) people, who are usually spearheading the data revolution as far as pharma is concerned, can work with these sub-optimal conditions but their highly specific skills can, and do, isolate them from the rest of the company. This can present new challenges because big data, of which RWD is a subset, has several applications in marketing as well as to create the best possible value proposition to secure or defend market access, the primary focus of most HEOR departments.

Big data and marketing

But big data provides an entirely new dimension not only to the evidence base for medicines but also to how that evidence is communicated, to whom it is communicated and, most importantly, how effectively that evidence can resonate with end users. It will be used to track patient pathways, patient attitudes, segmentation, personalisation of messaging, clinical trial recruitment, social media communications and sales rep activity.[12]

The challenges for pharma lie in aligning their various capabilities around what big data can deliver, in building bridges between the commercial, HEOR and R&D departments so that everyone can not only input their knowledge to a specific project but also know how to extract the information they need to perform at an optimal level.

Privacy challenges

This may be largely an internal communications exercise but the importance of real dialogue in the new order of things cannot be overstressed. Indeed, the issues surrounding who owns and what can legitimately be done with personal health data are a core focus for Manning. The NHS, with linked cradle-to-grave

12 Rowley, D. 'Health innovation: Big Ideas'. Retrieved at: http://www.pharmaphorum.com/articles/health-innovation-big-ideas.

data on all its patients, has an opportunity to provide the kind of RWD that can not only ensure a more efficient health service but, by selling it to pharma and other third parties, plug a large chunk of its financing shortfalls. But the care.data programme that was supposed to provide the basis of these RWD collection efforts was effectively derailed while concerns over NHS England's intention to use patient data for purposes beyond direct healthcare were ironed out. In particular, greater assurances were sought on issues such as patients' right to object, protecting privacy, the burden on GPs, and the controls around how data held by the Health and Social Care Information Centre (HSCIC) will be accessed and used.

"The richness of our data is unparalleled in any other country in the world," says Manning, adding that the debate sparked by care.data is a reflection of a massive loss of trust in public institutions and in the pharma industry. "People want to know why business should use this data for profit, how it gets used and is it traceable. These are legitimate questions and stem from the fact that the NHS is based on implicit consent."

The NHS is still based on this erroneous assumption. And while small pilot programmes to extract data are ongoing and efforts intensifying to educate the public on the value of this data, Manning says that the HSCIC has no answer to companies that are now springing up to buy people's healthcare data. "There is a venture capital company funded by Pfizer that is offering $2,000 a year for the health records of a healthy person and $15,000 a year if they have cancer," he explains. "We have no answer to that type of approach."

Conclusions

The brave new world of healthcare that is emerging is one characterised by connected and informed patients, a new agenda around people taking greater responsibility for their health, and the means for payers to know what works and what doesn't. Each aspect fundamentally affects how pharma operates. How pharma responds will differ from company to company as they play to their respective strengths. But the strands common to them all will be to move towards greater internal cohesion, a recognition of the importance of trust among the public and the creation of services, medicines and otherwise, that can build and solidify that trust.

No one can accurately predict how things will develop from here, such is the pace of change. However, there are strong hints emerging that the successful pharma company of the future will have to:

- Take a critical look at how technology can facilitate the flow of information in all its processes (both software and hardware) in order to drive process efficiencies.
- Embrace and support the development of technology that can extract the big data of health outcomes, in order to help it communicate clear value for its medicines.
- Broaden its field of vision further back into prevention and management of wellness, as new technologies enable more 'patients' to head off their disease in the early stages, or even before they become symptomatic at all.
- Develop meaningful partnerships with technology organisations (both medically-focussed and beyond) that can help deliver health solutions, whether they relate to medical products (value-added services) or not (true beyond the pill).

About the author

David Rowley is the CEO of OPEN Health, a healthcare communications and market access group. It is made up of specialist, best-in-class businesses, that individually are experts in their own fields. Currently, it is a group of around 200 people, operating across a wide range of disciplines. OPEN Health works with almost all of the world's top 40 pharmaceutical companies, as well as with many device, diagnostic and healthcare delivery organisations, from small start-ups to major multinationals at a UK, regional and global level.

David has over 25 years of healthcare marketing experience and has worked on both the agency and client side, most recently founding two healthcare communications agencies. Prior to this, his work within the industry saw him focus on global brand management and leadership.

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