

The Patient-Centric Movement

(Source: an article prepared by Hugh Gosling and published by Pharma Times)

There is a movement emerging throughout the pharmaceutical industry, with the power to fundamentally transform every function, every stage of the pipeline and every marketed product. This force is driven neither by cost containment nor regulatory pressure, it is neither a clever gimmick dreamed up by a management consultant nor a kneejerk reaction to a market dynamic. This force is the patient, the end-user of medicines, the person who has, in Europe at least, been far from the forefront of pharma thinking, according to the author. Starting from demographic shifts, incubated by increased transparency and nurtured by the internet, companies are only now starting to realize the incredible transformative power of their insights and, increasingly, their advocacy.

In March of this year, the industry gathered in Barcelona for the annual “eyeforpharma” conference, spending three days discussing the issue of patient centricity. Accordingly, what is patient centricity and how can engaging patients benefit pharma? In what ways can companies use patient insight to deliver better products and services? How can they engage patients without falling foul of regulatory agencies? Most importantly, what approaches work and what don't?

"Patient centricity has moved from a buzzword to a very sharp reality for the healthcare industry," says Martine Leroy, head of insight at creative marketing consultancy Blue Latitude Health. "There is a realization that unless they embrace patients, *(continued on page 2)*

2025 US Healthcare Costs Projected to be US\$2.7 Trillion

(Source: an article prepared by David Salazar and published by Drug Store News; Health Affairs)

Between 2015 and 2025, according a new article in Health Affairs, growth in U.S. health spending is projected to increase about 5.8% on average — a number that surpasses growth in the gross domestic product (GDP) by 1.3%. In 2016, the article projects that national health spending per capita will surpass US\$10,000 for the first time. Despite the cost per capita aggregate national spending growth, Medicaid (federal/state program for the poor) spending growth is expected to slow this year, to 5.3% from an average of 10.8% in 2014-2015, with an expectation in prescription spending growth of 4.9%. Private payers will also see steady low spending growth of 4.9%, down from 5.1% in 2015. Medicare (federal program for the aged), on the other hand, is expected to see its spending growth rise this year to 5.2%, an increase from the 4.6% growth it saw last year.

For the period from 2017 to 2019, the Health Affairs' report projects a rise in spending growth across sectors and payers, with national health spending expected to average 5.8% during that time, an increase over the 4.8% growth seen in 2016. Private payers will see their spending grow an average of 5.6%, Medicare will *(continued on page 2)*

In Brief . . .

- ◆ **McKesson** reported a 5% increase in revenues to US\$49.7 billion and net income of US\$542 million for its fiscal first quarter. Separately, **McKesson Health Solutions** recently released a national study which found that value-based reimbursement has firmly taken hold in the US but that payers and providers are struggling to operationalize some of the fastest growing payment models. In response, the company is acquiring **HealthQX** and the latter's **ClarityQx** value-based payment technology for an undisclosed sum. The move will enhance McKesson's ability to help customers rapidly and cost-effectively transition to value-based care by automating and scaling complex payment models, such as retrospective and prospective bundled payments.

- ◆ **Oriola-KD** (Finland) has acquired **Pharmaservice Oy**, a Finnish company that provides supporting services for automated dose dispensing of medicines to pharmacies in Finland and serves approximately 20,000 of the pharmacies' customers. In 2015, Pharmaservice had net sales of approximately €14 million / US\$15.5 million. The acquisition complements Oriola-KD's purchase of the Swedish dose dispensing company **Svensk Dos** in early 2016.

- ◆ **Teva Pharmaceutical Industries** has obtained U.S. antitrust approval to purchase **Allergan's** generics business in a deal valued at US\$40.5 billion, after agreeing to divest 79 products to 11 rival firms (representing the largest divestiture ever required by the US FTC under a pharmaceutical merger review). The transaction solidifies Teva's position as the world's largest maker of generics while freeing Allergan to focus on branded drugs.

- ◆ **Galenica Group** (Switzerland) will acquire the **Relypsa, Inc.**(US) for approximately US\$1.53 billion, thus strengthening Galenica's Business unit **Vifor Pharma** by adding a fully-integrated commercial organization in the US and significantly strengthen its presence in the US cardio-renal market, one of its key focal areas.

- ◆ **Walgreens Boots Alliance** is forming a franchise partnership with **Emart Company**, a member of **Shinsegae Group** and South Korea's No. 1 hypermarket retailer. Together, they will create a Boots branded pharmacy-led, health and beauty retail franchise in South Korea. Separately, Walgreens on will discontinue operations of **drugstore.com** and **Beauty.com** in favor of its online offerings at **Walgreens.com**.

- ◆ **Humanwell Healthcare Group**, a healthcare solutions provider headquartered in Wuhan, China plans to focus on the United States in the next 5 years through mergers and localized research, stating that “The advanced technologies and high standards in the US will help bring down costs, which will eventually benefit China's general public.” According to Bloomberg, Chinese firms have engaged in more than US\$3.9 billion in overseas acquisitions in the pharmaceutical, biotechnology and healthcare sectors in 2016, a pace on track to exceed last year's record total and a tenfold increase from the *(continued on page 3)*

Patient-Centric (cont.)

companies will face ever higher hurdles to get their products to market. However, the healthcare sector is not driving the change and pharma companies are not leading the way; they are reacting to events, creating new roles and are trying to innovate. They are spotting opportunities and pursuing them."

Some companies are reticent to fully commit to the transformation, says Paul Wicks, vice president of innovation at data sharing platform, PatientsLikeMe. A true patient-centric program requires a significant change to current processes. This generates the question, why should they do that and lose precious time in moving programs down the line?

Another barrier is when companies already think they are patient centric. "When I work with a pharma client, I look through their annual report to count how many pages I have to read before the word 'patient' is mentioned; my record is 26 pages," says Wicks. "For many, patient centrality has been nothing but tokenism.... We have to go past this level of tokenism to find out what the real opportunities are." He points to the tech industry. "In tech, there is a tradition of open source and transparency; a lot of senior people have Twitter or Facebook accounts or they blog about their work, even their failures. In tech, they agonize over whether they have delighted their customers but the pharma industry is optimized towards prescribers, payers, HTA bodies and regulators. Even though it is patients that use their products every day, industry has been slow to wake up to the fact that patients are their real customers."

Guy Yeoman, vice president of patient centrality at AstraZeneca, agrees. "As an industry we are very much focused on delivering for patients when we really need to start delivering with patients. It is not a difficult concept but in reality it's quite difficult to do from a behavioral perspective. Historically, we have gone to Health Care Providers (HCPs) to get the patient perspective, we ask what doctors think patients need and think, and that's not good enough now.

"There are some great examples of best practice [but] as an industry there is a lot we're doing that doesn't really work because it doesn't address underlying patient need. We don't engage patients as we should in our research agenda, we don't ask them about their experiences in a study so we sometimes struggle to recruit and retain them. There are big challenges in the R&D space and there are big challenges in the patient services space. Historically, we have been very focused on our own brand; we generate brand specific patient websites at a global level and replicated them at a country level, we generate adherence programs that focus on our brand, sending reminders to take our specific medicine. These all fail to address fundamental patient need and as a result patients don't engage with them," he says.

As companies venture into this new space, the important question is, what do patients want? For Andrew Schorr, two-time cancer survivor and president/founder of cancer patient community Patient Power, the answer is clear. "Patients want transparency. Help us to understand what's working and what isn't. Share results. Give us hope for a cure or a better medicine. Treat patients taking part

in a clinical trial as investors; they are investing their bodies in your trial so keep them informed about that investment. They also want to be thanked afterwards. These are basic things," he says. Pharma alone, however, cannot deliver everything that patients want. He says. "Pharma can't do everything but it can do more. Patients are not necessarily antipharma but until recently the industry has not been sitting at the same table in any meaningful way."

As with all fundamental changes that sweep an industry, patient centrality has left many wondering about how to proceed, says PatientsLikeMe's Wicks, but he has some advice. "There's a great academic framework called Arnstein's Ladder that was developed in the 1960s. At the bottom is nonparticipation, even manipulation, then it rises to tokenism, where participants have a seat at the table but their input can be ignored by others. Higher up the ladder is true partnership, where participants not only have a seat at the table but they vote on issues and even help to choose who else sits on the committee and what resources are allocated. Their opinions matter. At the very top is citizen ownership, where participants make decisions and have the power, which is a pretty radical model that industry might not be ready for. Pharma is probably more comfortable aiming for true partnership."

It will take time to build meaningful patient centric relationships, says Patient Power's Schorr. "The trust just isn't there at the moment and winning it is a big challenge. If you follow the US political chaos taking place right now, you'll hear Democratic candidates talking about pharmaceutical companies a lot. They say they need to be reined in, which in some cases is very unfair as there are many other quarters where costs need to be controlled. But pharma is portrayed as the bad guy, and examples like Turing give the impression that all companies are the same, which is certainly not true."

His advice to companies is to let go. "Companies that are serious about this agenda should aim to support the efforts of others and give up control, which means their agencies and PR firms and internal departments support, suggest and have a say, and those of us on the patient side have to listen. Companies with the leading science will win out in the end but only if they stop deciding that they think they know what patients want. So many attempts to develop relationships have used gimmicks, asking patients to sign up for and disclose their information, and these gimmicks are just sad. They are not a sustained effort to educate, support and empower communities, and patients recognize that."

For Schorr and other patient advocates, the long-term
(continued on page 3)

2025 US Healthcare Costs (cont.)

see average spending growth of 6.7% and Medicaid will see 5.6% growth on average. Medicare expenditures per beneficiary are also expected to rise from 1.8% in 2016 to an average of 3.7% from 2017 to 2019. In the five years between 2020 and 2025, the report projects a 7.6% spending growth average for Medicare, 5.2% for Medicaid and about 5% for private payers. As spending growth increases, so too will the amount of costs that federal and state governments absorb. Governments are expected to sponsor about 47% of health costs by 2025, or nearly US\$2.7 trillion by 2025, with households and business expected to cover 53% of costs. The report expects prescription drugs to have a smaller impact on health spending in the next 10 years than they did in 2014 and 2015, which it attributes to an expected drop in the number of approved new drugs, and the anticipated increase in availability of biosimilars.

**IF YOU HAVE NOT RETURNED YOUR BALLOT FOR
THE 2016-2018 TERM BOARD ELECTIONS,
PLEASE DO SO NO LATER THAN AUGUST 5TH**

Patient-Centric(cont.) . . .

solution lies in therapy area collaborations. "It is almost impossible for an individual company to deliver the 360-degree view that patients want; they need to partner. Some companies are starting to understand that a therapy area strategy is needed where they collaborate with the other guys as well as healthcare organizations, governments, charitable foundations."

One company that is sensitive to engage in this way is AstraZeneca. They have just begun the patient centricity journey but they recognize the need to work together across the healthcare sector. There are several public private initiatives helping to define the process of patient engagement in R&D, and that will drive a collaborative approach. As part of the process for AZ, they recognizing the need to engage more particularly in patient services, with device companies, for example, where they can pool combined expertise and resources so that when they develop a brilliant service they can scale it up much more efficiently than an individual company on its own.

For AZ, there is no onesizefitsall model. "Every company is trying to work out how to do this properly, and there are various titles, centers of excellence and roles. What AZ chose to do is to create a small group tasked with enabling the organization to become more patient centric, ensuring they deliver patient centric medicines and services quickly and efficiently. They are committed to shifting their organizations culturally on this journey. The final part is to start embedding it into their business processes, to ask what the patient centric component is in a medical plan, or a development plan, or a marketing plan. It is a significant transformational program and they are looking at three to five years to really start embedding it in their culture.

GSK has opted for the decentralized approach, says chief medical officer, Murray Stewart. "We've deliberately decided not to centralize it to make everyone feel a part of it, to make every part of the business think about the patient. For me and GSK, making sure the patient is at the forefront of everything we do is business as usual. As CMO my role is to remind the business that we're developing drugs to make a difference to people's lives. I try to get people in discovery to consider patients when thinking about targets and people in discovery or in medical affairs looking at the business in late stage to think about the patient. It is quite a challenge in big organizations to get everyone motivated and to think about process."

Novartis started with a clear vision and definition of patient centricity, says CEO of pharmaceuticals, David Epstein. "I took my executive team up a Swiss mountain where the air was thin and the sun was shining and they started to recount personal stories about their experience interacting with patients. It was totally unprompted but we spent the next day writing out what became the Novartis Patient Declaration, delineating our aspiration of what patients could expect from us."

At LEO Pharma, CEO Gitte Aabo built patient centricity into the 2020 strategy. "Our strategy, Helping Sarah, sends a signal to everybody in LEO that patients are individual people who live individual lives and have individual needs. It is crucial that we understand that if you have a chronic disease like psoriasis you don't think of yourself as a patient but as a person living with a skin disease, so we need to develop treatments that work in normal, everyday life. It may sound simple but the focus on the individual has a tremendous impact on how we act as a company; the better

you understand the patient, the more likely that the business follows."

The support programs LEO offers patients do not require them to be taking one of the company's medicines. "Our success criteria is to improve the quality of life of everybody with psoriasis; if we're really true to our mission of helping people achieve healthy skin, we must acknowledge that it takes more than treatment. If you listen to the CEO of Amazon talking about how they obsess about customers, it is the same philosophy I want to see in LEO; that we truly care about providing solutions to people living with skin diseases," says Aabo.

There are other pharma companies pursuing a patient-centric path. The real question will be: will the patient-centric programs being developed focus on the disease or the product?

In Brief (cont.) . . .

amount spent in 2012.

- ◆ **Aspen Pharmacare Holdings Ltd** plans to increase its Chinese presence, as Africa's biggest maker of generic drugs ramps up distribution of its low-cost pharmaceuticals in the world's most populous country. The South African company will add 350 sales representatives in China in the next few months and plans to later increase that to 500.

- ◆ In addition to leveraging a pipeline of complex generics across its markets while focusing on OTC, **Dr. Reddy's** recently indicated that branded generics would be one of the ways the company drives growth in the coming years, stating "We are creating a branded generics platform in North America and expanding our biologics play in Russia, CIS and other emerging markets."

(Sources: China Daily, Drug Store News, Galenica, Oriola-KD, Pharma Japan, Reuters and Scrip)

Spain's Pharmaceutical Industry Establishes Sevem

On July 26 in Madrid, the company that will manage the Spanish Drug Verification System (Sevem) was formed in response to the European Directive on Counterfeit Drugs and its Delegated Regulation. Sevem is required to be fully operational by February 2019. The signing of the organizational documents was attended by Spain's general secretary of Health, Javier Castrodeza, and the director of the Spanish Agency for Medicines and Health Products (AEMPS), Bethlehem Crespo.

The board of the new entity will be composed of the National Business Association of the Pharmaceutical Industry (Farmaindustria), the Spanish Association of Generic Drugs (AESEG), the General Council of Official Colleges of Pharmacists (CGCOF) and the National Federation of Wholesale Distributors Proprietary Medicinal Products and of cosmeceuticals (FEDIFAR). Spain's Competent Authority will also have supervisory functions of the system and it will be represented at all council meeting.

Key personnel for Sevem will be hired in September. At the end of the organizational meeting, Secretary General of Health, Javier Castrodeza, highlighted the great value of this measure. "Although Spain is one of the countries with the highest security in the distribution of medicines, we take this step to strengthen even more the guarantees," he said. He conveyed to the organizers the congratulations of the Minister of Health, Alfonso Alonso.