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Future Reflection Points for the Industry

(Source: A report prepared by IQVIA Institute for Human Data Science titled "2018 and Beyond: Outlook and Turning Points")

This report calls out ten predictions for 2018 and beyond. The following are excerpts that summarize the background of each. The full report is available at www.iqvia.com/institute.

Big Data. As Big Data gathered in real-world healthcare settings becomes more prevalent and robust, it is increasingly being used across the entire healthcare system for evidentiary purposes or as Real-World Evidence (RWE). Both granular and timely, this data – which includes electronic health records (EHRs), claims data, disease registries, among other sources – can shed light on the use, benefits and risks of medicines outside of clinical trials.

Next Generation Biotherapeutics move toward mainstream. Over the past few years, a new generation of cell-based therapies, gene therapies and regenerative medicines (e.g., Next Generation Biotherapeutics) have begun to complete clinical trials and gain regulatory approval, with agencies now categorizing and granting breakthrough designations for these types of therapies. These treatments stretch the definition of a drug by being engineered personally for each patient, and some offer curative results with a single administration. In certain cases, these characteristics also result in an extremely high-cost per patient relative to traditional, small molecule therapies.

Apps make their way into treatment guidelines. The proliferation of Digital Health tools, including mobile health apps and wearable sensors, holds great promise for improving human health. As with other new health technologies, evidence of their effectiveness is a fundamental requirement of the health system and a limiting first step to adoption into clinical practice. The growing acceptance of apps in healthcare is lagging behind popular culture as a direct result of the need to prove value with evidence and ensure integration into provider workflows.

Telehealth usage broadens. It has long been suggested that rising healthcare costs can be offset by addressing inappropriate use of primary care, urgent-care clinics and emergency rooms (ERs). Around the world, some countries have already made considerable progress using a mix of phone and internet consultations in an attempt to siphon off patients who could be described as misusing resources and encourage them to go to a more optimal site of care, or just stay home. Advocates of telehealth argue that most of the reasons to see a provider in person can be supported remotely, including capturing vital signs, and patient reported metrics such as quality of life, pain thresholds, etc. Policies that encourage 'right behaviors' or discourage the wrong ones have made some inroads, such as reimbursing providers less if they fail to reduce ER utilization or readmissions. Setting patient copayments higher for undesirable activities is an approach that payers have used, and some insurers are now disallowing ER reimbursement for certain events that could have been handled more cheaply, elsewhere. The cost differences are significant: an ER visit averages US$1,200, while an urgent care clinic visit averages 10% of that, an office visit or an in-store pharmacy clinic may cost US$50-US$150 and telehealth visits can cost US$50-80.

Branded medicine spending in developed markets falls. Over the past five years, branded drug net spending in developed markets has risen from US$326 billion to US$395 billion. This compares to invoice spending which rose to US$541 billion in 2017 from US$401 billion, five years earlier. The use of off-invoice discounts and rebates along with statutory price concessions required of manufacturers by governments or government programs result in net spending which is US$146 billion lower than invoice, and that difference has nearly doubled in the past five years. In total, 87% of the US$69 billion of net growth has come from the United States. In other developed markets, (Japan, Germany, France, Italy, Spain, United Kingdom, Canada, South Korea and Australia) where largely single-payer systems manage costs and prices, growth has been slower or declined since 2012.

Specialty medicines drive all spending growth in developed markets. The past decade has seen a sustained shift in the focus of new medicines towards specialty pharmaceuticals. These are defined as those medicines treating chronic, complex or rare conditions and also meeting a majority of seven additional

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- **AmerisourceBergen's ICS** unit, a leader in innovative distribution services for pharma manufacturers, announced the grand opening of its newest third-party logistics pharma distribution center in Ohio. The new facility will serve as ICS's flagship location and will further strengthen the company's already robust end-to-end integrated solutions for improving access to specialty drugs, as well as optimizing supply chain efficiency and enhancing patient care.
- Swiss drug maker **Bayer** is considering an overhaul of their drug research and development unit which would include job cuts and outsourcing. The company is under pressure from investors to either make purchases or institute licensing deals to ensure the long-term independence of the pharmaceutical division which would give them financial flexibility to ensure long-term independence.
- Canadian trade negotiators are reportedly pushing back on a requirement of at least ten years of data protection for biologic drugs, a move that would boost prescription drug prices for Canadian patients. Currently, biologics in Canada are protect from competition from follow-on or generic-like products for eight years. According to *Marc-André Gagnon*, a pharmaceutical policy researcher at Ottowa's Carlton University, a ten-year protection requirement would have an important impact on drug cost in Canada, especially with reference to the implementation of a national pharmacare system in Canada.

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2018 and Beyond (cont.)...

criteria which reflect varying interests of stakeholders. Specialty medicines may have costs exceeding US$6,000 per year or require some form of payment assistance. They also may require special handling in the supply chain or use highly specific distribution arrangements. Some medicines are considered specialty because they require administration by a healthcare provider or are initiated by a specialist or because there may be significant side-effects or treatment counseling required. Driven by new therapies and slowing or declining growth of traditional medicines, specialty share of global spending has risen from 19% in 2007 to 32% in 2017.

Slower growth in China and other pharmerging markets. The share of global medicine spending from pharmerging markets has risen from 13% in 2007 to 24% in 2017. This corresponds to an increase in spending from US$81 billion in 2007 to US$270 billion in 2017, with an average rate of 12.8%, more than twice the rate of global growth. Pharmerging markets will be driven by volume changes and the use of generics, and will grow by 7–8% in 2018, down from the 9.7% compound annual growth rate over the prior five years and marking the third year that growth will be less than 10%. The pharmerging markets are projected to grow by 6–9% to US$345–375 billion by 2022. China is the largest pharmerging country but will grow by only 5-8% over the next five years to reach US$145-175 billion in 2022.

U.S. real net per capita spending on medicines steadies. In a new era of value-based medicine, the price of a new drug is increasingly weighed against the value it brings; the time has passed when increasing the price of an existing drug is "allowed". While the vast majority of medicines in the United States are dispensed as generics with patient and health system costs below US$10 for a prescription, a small portion of medicines have costs that are far higher. An increasing proportion of patients have deductible insurance plans or high coinsurance rates that expose them to greater costs. Real net per capita spending on medicines in the United States will decline in 2018 and continue almost unchanged at almost US$800 per person through 2022

Outcomes-based contracts find limited role. A medicine's profile in terms of response rate and benefit on balance means that while some patients do not respond to the treatment, the ones that do justify the cost of the therapy. Historically, this has been a reasonable tradeoff for payers, partly because a nonresponding patient could simply stop treatment without incurring substantial costs. Long-term benefits of some newer medicines, such as a 'cure' with one shot, or one course of treatment, are often their key features, but those outcomes may not apply for all patients. Recently manufacturer and payer negotiations are including elements of pay for performance for high per-patient cost drugs, at least partly because significant costs can be accrued before a patient's response can be determined. The basic framework for an outcomes-based contract codifies a payment model linked to an administrative mechanism to adjudicate the outcome and therefore the value. The most common approach is to attach a discount to outcomes which are worse than those demonstrated in the pivotal clinical trials that are associated with regulatory approval. payers (or providers), as well as provide a degree of predictability.

New wave of biosimilar market opportunity emerges. Biotech medicines, produced through recombinant DNA technology from living cells, can never be exactly duplicated. As such, creating a generic version of biologics is impossible. Regulators, recognizing this, created the similarity threshold and have largely settled on harmonized definitions across developed markets. The part of the market subject to biosimilar competition remains a relatively small part of overall biotech spending because only seven molecules of the 196 currently marketed have faced biosimilar competition, to date. With the total market for biotech medicines reaching US$168 billion across developed markets in 2016, heightened interest is being placed on the role of biosimilars, which is set to expand significantly. There remain a number of challenges with biosimilars, in addition to the intellectual property, litigation, clinical development and regulatory hurdles that seem to be met by biosimilar manufacturers/companies with a high degree of success and without major issues.

In Brief (cont.)...

- U.S. pharma manufacturer **Eli Lilly** has promoted *Anne White* to the position of senior vice president and president of **Lilly Oncology**. She will replace the current oncology head, *Sue Mahoney*, who is retiring after 18 years.
- According to a report released by Japanese market research firm **TPC Marketing Research**, the global biologic market expanded to ¥18,604.4 billion (US$144.5 million) in FY2017, up 13.9% year-over-year. The U.S. was the largest market, accounting for 56.7% of market share. Europe was the second largest market, coming in at 23.5%. The Japanese market came in third with 6.4% of market share.
- U.S. drug manufacturer **Pfizer** estimates that it will cost US$100 million to adapt its supply chain due to Brexit. In its quarterly filing, Pfizer noted that its "preparations are well advanced to make the changes necessary to meet EU legal requirements after the U.K. is no longer a member state, especially in the regulatory, manufacturing and supply chain areas", a necessary move to ensure continuity of supply in the U.K. and Europe. According to Bloomberg, GlaxoSmithKline also estimated costs at US$100 million, and AstraZeneca has pegged its costs at approximately US$40 million.

(Sources: CBC News, China Daily, Company Press Releases, Economic and Political Weekly, FiercePharma, Pharma Japan, and Reuters)