

American Healthcare: Finding a Path to Meaningful Improvement

(Source: An article by Joshua Cohen for Forbes Magazine)

Moving American healthcare forward is challenging at a bare minimum. Politics tends to lead the conversations surrounding the direction of healthcare reform where nuance and compromise are needed to make progress of meaningful substance.

Last year's U.S. Senate hearings on drug prices and rebates were a good opportunity to air grievances by opposing parties, in this instance the pharmaceutical industry and pharmacy benefit managers. To date, a solution is still elusive, leaving patients with rising out-of-pocket costs.

Some states have passed laws aimed at providing the necessary pathway to more affordable healthcare and drugs, but most of these laws don't have the teeth to make a difference to the end consumer. For example, legislation passed does not require release of real transaction prices at each stage of the pharmaceutical distribution process. They only require revelation of something that was already public knowledge – the list prices named WAC (wholesale acquisition cost) and AWP (average wholesale price). The Centers for Medicare and Medicaid Services have attempted to open the books on hospital service pricing but information that has been disclosed often does not correspond to what is paid by the patient.

On a positive note, there is bipartisan support to end surprise billing, a phrase that refers to situations when patients receive exorbitant bills for healthcare that was out-of-network with their insurer. While proposed legislation for surprise billing failed in 2019, it could potentially be legislation that President Trump would be willing to sign in 2020. Main opposition to this solution comes from libertarian groups that oppose government interference.

Proposals that have become a hot button topic on the U.S. presidential campaign trail by Democratic candidates seem to lack the meaningful change necessary to improve the existing system. While these ideas are thought-provoking, the Medicare for All discussion is vastly expensive and disconnected from what the American voter views as realistic. There is very little chance that Medicare for All legislation would pass Congress. Yet, it is offered up as the only solution to the faltering Affordable Care Act. Furthermore, the United States Supreme Court has declined to hear arguments considering a legal challenge to the ACA until after the U.S. Presidential election in November of 2020. This means continued uncertainty for tens of millions of individuals who depend on the ACA for their healthcare coverage.

The U.S. healthcare system is one of many complexities, and it cannot be reformed in one broad brush stroke. Those who were hoping for answers to these complex challenges are still waiting. It is a situation that affects millions of Americans every single day. But until political and judicial gridlock is relieved in a meaningful way it will be incredibly difficult to carry out any meaningful change.

In Brief...

♦ U.S. wholesaler and pharma distributor **McKesson** reported consolidated revenues of US\$59.2 billion, an increase of 5% year-over-year, for the third quarter of 2019. For U.S. pharmaceutical and specialty solutions segment, revenues increased 6% to US\$46.9 billion with a third quarter operating profit of US\$687 million. Operating margin was 1.46%. European pharmaceutical solutions segment was flat at US\$6.9 billion.

♦ **AmerisourceBergen Corporation** reported revenues of US\$47.9 billion for the first quarter of 2020 (ended December 31, 2019), a 5.4% increase year-over-year. "We delivered strong revenue and adjusted EPS growth in the first quarter of fiscal 2020, driven by both the pharmaceutical distribution and global commercialization services and animal health groups," said *Steven H. Collis*, Chairman, President and CEO of ABC. "Our results continue to demonstrate the strength of AmerisourceBergen's unique pharmaceutical-centered strategy and compelling position in the U.S. market," said Mr. Collis. Separately, the company announced that it will be closing its compounding pharmacy business, Illinois-based **PharMEDium**, by the end of this year, impacting approximately 1,000 employees in four states.

♦ U.S. wholesaler and distributor **Cardinal Health** today reported financial results for the second quarter of fiscal 2020

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The 10 Most Anticipated Drug Launches of 2020

(Source: An article by Kyle Blankenship and Angus Liu for Fiercepharma)

With the new year comes another round of new drug launches sprinkled with the blockbuster hopefuls. EvaluatePharma has assembled a list of the top ten most-anticipated new drugs based on estimated global sales in 2024. Of those ten, possibly eight could reach blockbuster status in four short years.

AstraZeneca and Daiichi Sankyo's breast cancer conjugate, *Enhertu (fam-trastusumab derustecan-hxki)* is the only one on the list that has received approval by the U.S. Food and Drug Administration thus far. The HER2-positive cancer therapy shrank tumors in 61% of patients during a Phase 2 trial, putting its possible revenue at a chart-topping US\$2.4 billion in 2024. AstraZeneca is betting up to US\$7 billion on the drug's success.

Rounding out the top five are drugs from Bristol-Myers Squibb, Novartis, FibroGen and Immunomedics and the group has some very interesting back stories. For instance, *sacituzumab govitecan*, a TNBC therapy with an estimated US\$1.44 billion in sales by 2024, was pushed back by the FDA in early 2019 due to issues at a manufacturing plant. The fallout included a shakeup at the company but has since been refiled and sees high potential for its FDA decision date in June.

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Novartis' *inlisiran*, which was acquired in a much-discussed US\$9.7 billion acquisition of the Medicines Company in December has suffered through highly-publicized difficulties by *inlisiran*'s PCSK9's predecessors from Amgen, Renegeron and Sanofi.

The bottom tier of the list is populated by what are expected to be lesser performers, but nonetheless interesting in their own right.

The entire list, in order, includes: 1. *Enhertu*, 2. *Ozanimod*, 3. *Inclisiran*, 4. *Roxadustat*, 5. *Sacituzumab govitecan*, 6. *Filgotinib*, 7. *Palforzia (AR101)*, 8. *Valoctocogene rosaparovect*, 9. *Rimegepant*, and 10. *Risdiplam*.

The Latest Update on the Coronavirus

The World Health Organization (WHO) declared the outbreak and spread of the 2019-nCoV a global health emergency late last week. Infections (which is nearly doubling in number of cases daily) has quickly risen to more than 28,000, including 563 deaths. WHO is working closely with global experts, governments and partners to rapidly expand scientific knowledge on this new virus and track the spread and virulence of the virus. It is also focused on providing advice to countries and individuals regarding measures to protect health and prevent the spread of this outbreak.

Despite efforts to contain the virus, confirmed cases outside of China are now reported in 28 countries, including many parts of Asia, Indonesia, Australia, North America, Europe, Russia, and the Middle East. Currently there is one confirmed death outside of China (a forty-four-year-old male in the Philippines) but it is only a matter of time before the death toll outside of China increases. One previously infected person has been released from a U.S. hospital in Washington state and is now under home quarantine.

Given the novelty of the virus, scientists are still uncertain about the virus' transmission behavior, including its spread among asymptomatic cases, although it has been established the virus can transmit between humans among close contacts and health workers. The incubation period for the virus can be as much as two weeks, which means there may be an exponential amount of people already infected that have yet to show symptoms. There is also fear that antibodies may not remain in humans long-term, and there is the possibility of re-infection even after an individual has had the virus.

The Chinese government is constructing hospitals specifically for the care of its infected population. Cities such as Hong Kong are demanding that all travel between mainland China and Hong Kong be stopped to keep the virus from spreading. All flights from the U.S. to China have been grounded, and four U.S. military facilities are being used to quarantine travelers coming from China to the U.S. until they can be cleared as a carrier of the virus. Likewise, a growing number of countries have advised their citizens to avoid all non-essential travel to China and many have announced screening measures for passengers from China, including the major airport hubs of Dubai and Abu Dhabi.

A series of tweets, published last week Tom Inglesby, director of the Johns Hopkins Center for Health Security, made recommendations for global and national planning efforts on what should be done in the event that the virus cannot be contained. He also called for a major expansion of personal protective gear for healthcare workers, hospital infection control plans, and the need for governments to provide transparent, comprehensive, and rapid

communications on the spread of the virus.

While a possible vaccine is still as far as a year away, companies such as Inovio Pharmaceuticals, Janssen Pharmaceuticals (a subsidiary of Johnson & Johnson), GSK, Gilead, Moderna, and Novavax are reported to be developing coronavirus vaccines. A total of 30 therapies are planned to be tested, including some traditional medicines, by Chinese scientists. Meanwhile, clinical-stage biotech company GeoVax signed a letter of intent with BravoVax, a vaccine developer based in Wuhan, China, to jointly develop a coronavirus vaccine using genetic sequences of the 2019-nCoV. HIV drugs currently on the market are also being used to treat patients with the virus and on February 5th, there were unconfirmed reports of repurposed drugs previously used for SARS and MERS being successfully used to treat the virus.

CBS News partner network BBC News said researchers at the Peter Doherty Institute for Infection and Immunity in Australia have recreated the "novel coronavirus 2019" strain outside of China. Chinese researchers have also duplicated the virus, but BBC said they have only shared its genome sequence with the World Health Organization. The Australian researchers said they would provide the duplicated virus to the WHO to assist in efforts to diagnose and treat it. Researchers at the specialist lab in Melbourne told the BBC they were able to grow a copy of the virus from a sample taken from an infected patient.

In Brief (cont.)...

ended December 31, 2019 with revenue at US\$39.7 billion, an increase of 5% from the second quarter of last year. "With the first half of the year behind us, we are raising our fiscal year 2020 guidance," said *Mike Kaufmann*, CEO of Cardinal Health. "This increase was driven by improved performance across our Pharmaceutical segment, particularly within our generics program. As we look forward, we remain focused on executing our strategic growth initiatives."

- ◆ **Amgen Inc.** confirmed that it will purchase a 49% stake in its Japanese joint venture **Amgen Astellas BioPharma KK** currently held by **Astellas Pharma, Inc.**, effective April 1st. This will convert the Tokyo-based operation into a wholly owned affiliate. Astellas initially used its development and marketing capabilities to get the products to market, while participating financially, and Amgen benefited from a strengthened commercial presence. The venture has already launched *Repatha (evolocumab)* for familial hypercholesterolemia and those with hypercholesterolemia and high cardiovascular risk.

- ◆ Pharmaceutical manufacturer **Allergan** has agreed to sell two of its drugs – *Brazikumab* and *Zenpep* – to **Nestlé** and **AstraZeneca** to satisfy regulators ahead of its US\$63 billion merger with **AbbVie**. The closing of both acquisitions are contingent upon receipt of Federal Trade Commission and European Commission approval, closing of AbbVie's pending acquisition of Allergan and the satisfaction of other customary conditions.

(Sources: Company Press Releases, Endpoint News, FiercePharma, TheStreet.com, and Yahoo Finance)