



The U.S. Managed Care Environment, An Attractive Market for Japanese Manufacturers?

(Source: An article by Eric Persoff for Pharma Japan)

Healthcare in the U.S. is a highly charged subject, with arguments for broader government-sponsored access at one end of the spectrum and a more free-market approach at the other end. The U.S. market has typically been the primary target for overseas expansion and globalization for Japanese biopharmaceutical manufacturers, the ongoing evolution of the managed care environment has created uncertainty around the sustainability of U.S. price levels and growth. This has led to questions about the viability of the U.S. as a target for global expansion.

While the current attractiveness of the U.S. market is still strong, Japanese manufacturers need to keep pace with market dynamics, including changes in industrial organization and consolidation of key stakeholder entities, as well as ongoing regulatory and policy changes, to ensure long-term return on investment. A recent example is the passage of the Inflation Reduction Act, with its provision allowing for direct price negotiation of selected drugs by Medicare and making Medicare a crucial stakeholder, one to whom biopharma manufacturers must be prepared to articulate the value proposition of their drugs.

The U.S. health insurance market uses a mix of both private and public channels. In 2020, 66.5% of patients were covered by private insurance; 34.8% held public insurance and 8.6% had no insurance. A unique aspect of the U.S. healthcare market is how the private market accounts for the majority of patient lives. Other major countries use systems that are entirely or largely subsidized by the government. There is debate about if the government should play a more significant role. Indeed, there have been numerous attempts to reshape the government's role in the past 20 years. Recent administrations have considered the so-called "Single Payer" model, and enacting price controls, as well as importing lower cost drugs from abroad.

These visions on how to reshape healthcare have proved difficult. One possible reason is due to the overall American legislative process. When social, economic, and financial issues are simultaneously addressed, the result often is compromises on key healthcare agenda points.

Managed care's objective should be to serve as a "health care delivery system organized to manage cost, utilization, and quality", leading to increased horizontal and vertical consolidation for two reasons, one being that through mergers, better efficiency can be attained as duplicated services can be eliminated. The second reason is that by growing vertically and horizontally, both payers and providers can gain stronger financial leverage and bargaining power. These mergers fall under three types, each with their own

(continued on page 2)

In Brief...

◆ **AmerisourceBergen** (ABC) announced it would acquire **PharmaLex Holding GmbH**, specialized services provider for life sciences industry, for US\$128 billion. PharmaLex would be acquired from funds advised by **AUCTUS Capital Partners AB** and subject to certain customary adjustments. This expands ABC's global platform of biopharmaceutical services, and PharmaLex's results will be reported as a component within ABC's international healthcare solutions segment. Separately, ABC has signed a US\$19.8 million deal with the U.S. government to increase the number of weekly shipments and delivery locations of **Bavarian Nordic's Jynneos** and **Siga's TYPOXX** monkeypox vaccines.

◆ **AstraZeneca's Evusheld** (a long-acting antibody combination of *tixagevimab* and *cilgabimab*) has received approval as a COVID-19 treatment worldwide, with its first approval in Japan. The Japanese government will purchase 300,000 units from AstraZeneca amid global supplies that have been limited due to the surging need for the drug. It was also approved for prevention (pre-exposure prophylaxis) of the disease, the same indication for which the product has already been approved in Europe and in the U.S. under emergency use authorization. Japan's health ministry also approved the production and sale of vaccines against the Omicron variant of COVID, with the government to send shots to local municipalities beginning September 19th.

◆ U.S. wholesaler **Cardinal Health** announced that **Debbie Weitzman**, current President of its Pharmaceutical Distribution, will become Chief Executive of its Pharmaceutical Segment. The appointment coincides with the resignation of the current CEO of the pharma division, **Victor Crawford**, effective September 19th. Crawford will remain with the company until November 17th to support the leadership transition. The company has reorganized its structure, with both the Pharmaceutical and Specialty Distribution businesses now directly reporting to Weitzman. The role of President of Pharmaceutical Distribution has been eliminated. The announcement comes after the company disclosed several initiatives to create shareholder value following an agreement with activist investor **Elliott Investment Management L.P.**

(continued on page 2)



IFPW'S GMM IN MILAN IS JUST A MONTH AWAY. DON'T MISS OUR PREMIER BIENNIAL EVENT!!

Click [HERE](#) to register today!
For more info contact Christina Tucker at c.tucker@ifpw.com

U.S. Managed Care (cont.)...

implications.

1. *Horizontal consolidation among commercial payers.* Commercial insurance companies, notably the top five – United Health, Anthem, Aetna, Cigna, and Humana - have grown through acquisition of smaller payers. However, further consolidation of these companies is unlikely due to the fact that some attempts were blocked on the basis of antitrust grounds. This concentration of patients into a small number of commercial payers has led to these payers having a disproportionate influence, not only in discounting and rebating negotiations with manufacturers, but also in determining which treatments, specialists and facilities patients will have access to for treatment. As the commercial payer industry has horizontally consolidated, key account management for each individual payer with an enterprise-level engagement strategy targeting numerous individual stakeholders within each payer has become more important than ever.

2. *Horizontal and vertical consolidation among healthcare providers.* The second type of consolidation among healthcare providers is both horizontal and vertical, including consolidation of hospitals, as well as specialty pharmacies being consolidated with hospitals. Specialty drugs are a significant source of revenue, and there has been increasing vertical integration with provider networks acquiring specialty pharmacies. Over 40% of mid-to large-sized hospitals have specialty pharmacies. As such, specialty pharmacies play an increasing role in distribution of high-cost drugs. The consolidation of hospitals and specialty pharmacies can increase access for specialty drugs under limited distribution networks. The key implication for manufacturers is that customer engagement has evolved to engagement with larger scale healthcare provider organizations. Manufacturers must interact not only physicians, but also administrators and healthcare provider organizations.

3. *Vertical consolidations among payers and providers.* This third type of consolidation involves the payers and providers into so-called "payviders". The model originates in Kaiser Permanente and could be the biggest concern for pharma manufacturers. The payvider model can be realized through partnerships that results in the creation of their own insurance plans, or payers being a provider.

There has also been increasing vertical integration between payers and specialty pharmacies with pharmacy benefit manager-owned pharmacies now occupying more than three quarters of the specialty drug revenue. These types of consolidation can potentially have a significant impact on manufacturers.

As the U.S. pharmaceutical market continues to evolve, the resulting changes in healthcare policies and stakeholder dynamics for manufacturers will also evolve in challenging ways. However, the U.S. continues to be the largest and fastest growing healthcare market with U.S. prescription drug spending reaching US\$577 billion in 2021. The U.S. market is also estimated to grow at 2.5-5.5% annually, reaching approximately US\$700 billion by 2026. Considering that Japan is expected to have negative growth of 2.0%-1.0% between 2022 and 2026, the U.S. remains a highly attractive market for Japanese manufacturers who are willing to invest and develop their presence.

Also, the strong pricing potential of branded drugs supports the attractiveness of the U.S. market. On average, branded drugs were priced three to four times higher in the U.S. than in other countries. Launch prices of all new drugs in the U.S. have increased by over 20% per year since 2008. Although generics and biosimilars are priced slightly lower, the higher price point and the continuing growth for new branded drugs would still be an attractive source of revenue for global manufacturers.

In Brief (cont.)...

- ◆ **Walmart and UnitedHealth Group** announced an initial 10-year collaboration that will bring the two companies' collective expertise of serving millions with affordable health services that improve health outcomes and the patient experience. Beginning in 2023, the rollout will be in 15 Walmart health locations in Florida and Georgia. The end goal is serving seniors and Medicare beneficiaries in value-based arrangement through multiple Medicare Advantage plans.

- ◆ **CVS Health** announced that will acquire healthcare company **Signify Health** for US\$30.50 per share in cash. The total transaction is valued at US\$8 billion. Signify provides technology and analytics to assist with in-home patient care and has a network of more than 10,000 clinicians across all 50 states including physicians, nurse practitioners and physician assistants who make home-based visits to identify a patient's clinical and social needs. They will then connect them with appropriate follow-up care and community-based resources. The deal is expected to close in the second half of 2023, pending regulatory and shareholder approval.

- ◆ U.S. online retail leader **Amazon** is considering entering the prescription drug sales business in Japan. Amazon plans to partner with small and medium-size pharmacies to create a platform where patients can receive online instructions on how to take medicines. Amazon aims to launch the service next year when electronic prescriptions will be authorized in Japan. The company will not operate its own pharmacies or carry inventory.

- ◆ **Novartis** is planning to spend up to US\$300 million to expand its development and manufacturing operations to bolster its push into biologic medicines. The company, which recently has been engaged in cost-cutting efforts, said it will spend US\$110 million to increase clinical manufacturing operations at its facility in Slovenia, and another US\$60 million to expand capacity at its site in Austria. In addition Novartis plans to establish a biologics hub at its Basel, Switzerland campus to complement an existing Novartis Institutes for BioMedical Research Center. The investments are part of Novartis' efforts to weave its early-stage biotherapeutics portfolio into existing locations.

- ◆ The U.S. government expects to bow out of the distribution of COVID-19 vaccines and treatments, handing the countermeasures to the commercial market. The government-led vaccine initiative has been offering vaccines and therapeutics to healthcare providers for free. Once the commercial market opens up, biopharma companies will have more access to more distribution channels.

(Sources: Associated Press, Company Press Releases, Store News, FierceBiotech, FiercePharma, Scrip Intelligence and World Pharma News)