

Amazon's Battle for the Prescription Drug Business Through Its Acquisition of PillPack

(Source: An article by Robert Langreth for Benefit News)

When Amazon bought the mail-order startup company, PillPack, at a price tag of US\$753 million, it wasn't obvious, at the time, that the hard part of venturing into the pharmacy business would be prying patients away from their local drugstore/pharmacy. Since its acquisition, PillPack has run into opposition from chains like Walgreens and CVS (both with thousands of storefronts) as well as family-owned pharmacy operations with a single shop. These brick and mortar stores are working hard to keep the likes of PillPack from chipping away at their slice of the US\$333 billion "pie" that makes up the U.S. prescription-drug industry.

PillPack's business model is simple. It offers patients who take multiple medications the option of replacing the typical drawer full of pill bottles with a neatly sealed packet stamped with the time that the medication is supposed to be taken. Complicating the process though is the fact that PillPack needs to ask a patient's pharmacy or doctor to transfer their prescriptions. In theory, this should only involve a faxed request from Amazon to the prescriber or pharmacy, but it didn't take long for Amazon to realize that the prescription transfer requests were being slow-walked or disregarded once the request was made. Typically, PillPack's technicians conduct a follow-up call, but found that pharmacists are "literally hanging up the phone without saying anything, which happens probably daily," said TJ Parker, PillPack's 33-year-old co-founder and chief executive officer.

This is a departure from when the company was in its infancy, according to interviews with three former PillPack technicians (who requested anonymity due to the sensitive nature of the interview). But once PillPack was on the radar of the big chains, it became exponentially more difficult as drugstores increasingly insisted on direct confirmation from the patients.

Patients who require multiple medications are a huge and lucrative market because pharmacies are often paid a fee or markup on each prescription. An estimated 23.1% of population – more than 70 million patients – take three or more prescriptions per month, and 11.9% take five or more drugs each month, according to the U.S. Centers for Disease Control and Prevention. This is the key market segment for PillPack. They are also the customers that the brick and mortar pharmacies are fighting to keep.

Amazon is partnering with JP Morgan Chase and Berkshire Hathaway in an employee health venture, but unlike its online bookselling business (they didn't need to pursue permission to sell online books) the company needs acquiescence from the very pharmacies it hopes to replace. These pharmacy retailers say that delays in processing are because they are trying to verify that these customers agreed to have their prescriptions transferred. PillPack maintains that they always get consent and that the chains are

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- ◆ **Walgreens** is partnering with **Alphabet's Wing Aviation** to make drone delivery of items from Walgreens stores a reality. Starting next month, consumers in Christiansburg, Virginia will be able to order items from Walgreens using the Wing app for delivery within minutes via drone. Walgreens stated that the pilot would be used to explore the future of health-and-wellness product and retail delivery by air. The companies selected Christiansburg as the test market because Wing has been working closely with Virginia Tech in nearby Blacksburg to test drone delivery as part of the Department of Transportation's pilot program since 2016.

- ◆ **Abbott Laboratories** entered into a collaboration with biopharmaceutical manufacturer **Sanofi** that integrates glucose sensing and insulin delivery technologies which would help further simplify the management of diabetes. The companies plan to adopt a pioneering approach to connected care by developing tools that combine the revolutionary FreeStyle Libre technology with Sanofi's insulin dosing information for future smart pens, insulin titration apps and cloud software.

- ◆ **Pfizer** is in the planning stages to establish a multinational network of digital research hubs with a focus on artificial intelligence and big data analysis. The first facility will be located in Thessaloniki, Greece and will concentrate on developing tech that can be incorporated into its development pipeline of medicines and vaccines. The facility will be the first of six and will be operational by 2020.

- ◆ According to *Alan Thomas*, director of Thought Leadership at **IQVIA Solutions Japan**, the Japanese pharmaceutical market is expected to shrink at a CAGR of 0.7% over the next five years (FY2019-FY2023.) The decrease is attributable to products losing exclusivity and drug price revisions. Speaking at a media seminar on September 4th, Thomas pointed out that

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India and China Spark Concerns over U.K. Drug Supplies

(Source: An Article by Emma Wilkinson for the Pharmaceutical Journal)

In a Parliamentary report on the impact of Brexit on the pharmaceutical sector (published in May of 2018) it was highlighted that 80-90% of generic medicines used by the U.K.'s National Health Service (NHS) are imported, with China and India among the top five providers of medicines provided outside of the European Union. Recent breaches at drug manufacturing sites in both countries are now raising questions about the efficacy of these medications, and whether it is time to repatriate production of critical drugs back to the U.K.

As an example, *Valsarta* (a frequently prescribed blood pressure medication) was found to have traces of potential carcinogens in batches manufactured at a plant in China. The

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purposefully stonewalling them in order to keep their customers trapped in an outdated and inefficient retail model.

Efforts by PillPack to work around any stall tactics are ramping up and include following up all faxed transfer request with phone calls. They are also contacting doctors directly to ask that new prescriptions be written for the patient as an alternative to getting the current prescriptions transferred. Additionally, the company is carefully tracking pharmacies that they suspect of being purposely uncooperative. While state laws in the U.S. do vary, most require that any prescription transfer requests be fulfilled.

Drugstores deny slowing down the transfer process. CVS said that it processes all transfer requests “legitimately requested by patients,” company spokesman Michael DeAngelis said in a statement. “Last year we notified PillPack to stop any activity to initiate prescription transfers without the informed consent of our pharmacy patients.”

Walgreens issued a statement saying, “In the event there is a question as to whether we have a patient’s consent, we do validate those requests with the patient.”

In 2018, CVS and Walgreens sent cease-and-desist letters to PillPack, warning the company against transferring customers without their consent. Since then, both companies have taken steps to ensure that patients really want to switch their prescriptions to PillPack. In June of 2019, CVS obtained a federal court injunction preventing a former senior vice president from working at PillPack, alleging the executive would have provided sensitive pricing data to a competitor.

In July, Surescripts, an electronic prescribing network owned by CVS, Cigna’s Express Scripts unit and two drugstore trade groups, cut PillPack off from a prescription-history database it had been obtaining from a third-party vendor. The matter was referred to the FBI alleging misuse of the information by the vendor on behalf of PillPack. PillPack denies any wrongdoing.

India and China (cont.)...

discovery of the organic lubricant, *N-nitrosodimethylamine*, an active pharmaceutical ingredient (API) in *Valsarta*, prompted a massive global recall from multiple manufacturers. Immediately following a review by the European Medicines Agency (EMA) 24 countries across Europe, the Middle East and North America recalled approximately 2,300 batches of the product. Subsequently in September of 2018, concerns were brought forward about contamination from a second *nitrosamine (N-nitrosodiethylamine)* also found in *Valsarta* products. Further testing and implication of other manufacturing sites led to additional recalls in December of 2018. There is credible fear that this is an ongoing issue.

An investigation led by the U.S. Food and Drug Administration showed that while the overall risk was small, it was “deeply concerning” considering the contamination went undetected for so long. It was also uncovered that systemic issues with supervision during the manufacturing process may have created conditions resulting in the occurrence of quality issues.

Gino Martini, chief scientist at the Royal Pharmaceutical Society, said “There does seem to have been a spate of inspectors going in [to Chinese and Indian manufacturers] and finding problems, and that is a good thing because it shows the system is working. But we do need to make sure there are regular inspections

to the same standard that manufacturers in the U.K. would get.”

The director general of the British Generic Manufacturers Association, Warwick Smith, explained that the production of both finished product pharmaceuticals and APIs has been concentrated in India and China for several reasons, including looser patent rules and an effort by manufacturers to keep costs down. “That is what should keep people awake at night,” he stated, “if you only have one or two manufacturers for APIs for a critical product, that is a real weakness in the supply chain.”

While quality data on the concentration of API manufacturers is nearly impossible to glean, some data that is available does give a bit of perspective. Estimates of APIs for medicines sold in the U.S. hover around 40%. Additionally, if warning notices by the FDA are an indication of the scale of production in India and China (18 letters have been issued since the beginning of 2018), then it is noteworthy that nine have been issued to Chinese manufacturers and five have been issued to companies in India.

Smith estimates that 50-60% of finished medicinal products dispensed in the U.K. are made in the EU, adding that he would like to see a wider variety of companies from around the globe represented in the mix.

Regulators from Europe, Australia, the United States and the World Health Organization are joining forces to address these concerns with more inspections of API production in other parts of the world. Between 2011 and 2016, inspections were carried in a number of locations, with 49% of said inspections being carried out in India and 36% in China. There was little evidence to suggest that standards are lower in India and China. According to the FDA, ratings for factories in Europe and the U.S. had the highest ratings at 7.9 and 7.7 out of 10 (respectively), compared with 7.0 each for China and India.

Still, *Valsarta* was an eye opener due to the fact that one company makes the majority of APIs for that particular drug. Due to the contaminant that was found, eight different formulations of the drug had to be removed from the market.

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while the market of NHI price-listed drugs was valued at more than 10 trillion yen (US\$92.5 billion) in FY2018, it would fall below that mark by FY2023.

- ◆ **Walmart** opened its first stand-alone U.S. health and wellness center in Dallas, GA. The clinic will include primary care services as well as a lab, x-ray, EKG, counseling, dental, optical, hearing and community health services, including fitness and nutritional consultation services in partnership with local providers.

- ◆ **Sanofi** is partnering with mental health digital therapeutics firm **Happify Health** with a proposed app to improve mental health in patients with multiple sclerosis. The app is currently in a proof-of-concept online trial that includes several thousand MS patients and is Sanofi’s first proposed digital therapeutic. Sanofi purposely chose MS as an entry point due to its extensive experience with the disease. The software platform was developed by Happify and is already used for a non-specific solution for anxiety and depression.

(Sources: Drug Store News, Fierce Biotech, Fierce Pharma, Pharma Japan, and Yahoo Finance)