



The U.S. Opioid Crisis and the Wholesaler

(Sources: IFPW's GMM and an article prepared by Larry Penkava and published by the Courier-Tribune, Asheville, North Carolina)

The importance of influencing, if not controlling, the news media's narrative – in this case on the Opioid crisis in the U.S. – was a message delivered by John Gray, CEO of Healthcare Distribution Alliance (HDA), at IFPW's General Membership Meeting held in Washington, DC October 11th & 12th.

A wave of opioid-lawsuits has been filed against the pharmaceutical industry's supply chain by city, county and state governments, alleging that pharmaceutical wholesalers/distributors are complicit in the opioid abuse crisis. An estimate by Bloomberg Intelligence analysts sets the potential cost as high as US\$50 billion for the entire industry. Unfortunately, the role of full-line, full-service wholesalers in this terrible crisis is highly misunderstood, resulting, in part, from the breakdown of relationships between the industry and the federal government's Drug Enforcement Agency (DEA). The DEA has controlled the media narrative on this issue.

The industry has responded to negative press coverage by initiating programs to assist in the elimination of opioid abuse. Cardinal Health, for example, gave this year US\$35,500 to a non-profit in hard-hit Clermont County, Ohio, where overdoses have soared for more than a decade. In all, the company has given at least US\$3 million to some 70 groups. Additionally, McKesson seeded a stand-alone non-profit dedicated to fighting the opioid abuse crisis with US\$100 million, and AmerisourceBergen (ABC) started its own opioid-focused grant program. ABC said it is still processing most applications but has announced a US\$50,000 grant to three Boise-area hospitals to launch a program to help patients who overdosed on opioids.

The industry's trade association, HDA, is pursuing an effort to inform the public on the wholesaler's role in delivering pharmaceutical products to healthcare sites, such as hospitals, retail pharmacies, clinics, etc. The following is a copy of a letter sent by John Parker, senior vice president of the Healthcare Distribution Alliance, to a North Carolina local newspaper, The Courier-Tribune:

“As distributors, we understand the tragic impact the opioid epidemic has on communities across the country. We are deeply engaged in the issue and are taking our own steps to be part of the solution — but we aren't willing to be scapegoats.

“Distributors are logistics companies that arrange for the safe and secure storage, transport and delivery of medicines from manufacturers to pharmacies, hospitals, long-term care facilities and others based on prescriptions from licensed physicians. We

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In Brief...

♦ U.S. wholesaler McKesson Corporation reported its fiscal second quarter results for 2019, with revenues of US\$53.1 billion, up 2% year over year, also up 2% on a constant currency basis. For the first half of the fiscal year, the company generated cash from operation of US\$318 million, and invested US\$248 million internally, resulting in free cash flow of US\$70 million, ahead of company expectations. “While our operational performance reflects anticipated challenges coming into the fiscal year, our second quarter results were primarily affected by the incremental headwinds we are facing in the U.K. and French markets, driving underperformance versus expectations. We continue to have conversations with the U.K. government to discuss the patient-care services that pharmacies provide and how this low-cost setting of care is vital to the healthcare system,” said McKesson Chairman and CEO John Hammergren. On late Thursday, November 1st, McKesson announced that Hammergren will retire after nearly 20 years at the helm. Chief operating officer (and IFPW board member) *Brian Tyler* will take over the position of President and CEO in March 2019, and independent Director *Edward Mueller* will assume the role of Chairman. Separately, the company announced that it has relaunched its biopharmaceutical services business under its U.S. Pharmaceutical and Specialty health business unit as McKesson Life Sciences. The new structure not only reflects its commitment to

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Blockchain Technology: The Next Generation of Supply Chain

(Source: Edited excerpts from an article prepared by Carly Guenther, managing director at Accenture Life Sciences, and published by PharmaExec.com, titled “In Blockchain We Trust”)

With many serialization and track and trace regulations in the compliance period, and others (e.g., EU FMD, US DSCSA) on the horizon, life sciences companies need to think beyond serialization as a core capability and prepare for the next generation of supply chain. Verifying the provenance of a medicine—from where its ingredients were made and where the drug was manufactured, to how the medicine was handled through the end-to-end supply chain and all the way to the patient in a trusted manner, is becoming an increasingly mandatory supply chain capability. That scenario is now possible using blockchain technology.

In one aspect of the life sciences supply chain, cold chain logistics take center stage. This series of uninterrupted

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Opioid (cont.)...

don't make medicines, market medicines, prescribe medicines, or dispense them to consumers.

"Given our role, the idea that distributors are solely responsible for the number of opioid prescriptions written defies common sense and lacks understanding of how the pharmaceutical supply chain actually works and how it is regulated.

"We are ready to have a serious conversation about solving a complex problem and are eager to work with political leaders and all stakeholders in finding forward-looking solutions."

Blockchain... (cont.)...

temperature-controlled, refrigeration, production, storage, and distribution of products is complicated and expensive. The pharmaceutical industry expects to spend nearly US\$17 billion by 2020 on cold chain management. When applied to the cold chain, blockchain combined with technologies like IIoT (Industrial Internet of Things) can create secure documentation of storage temperatures at every point in a product's journey. This enables supply chain managers and executives to identify potential temperature excursions and other efficiencies across the end-to-end supply chain and presents an opportunity to the challenges posed by CAR-T, as previously mentioned [in the article]. Additional opportunities exist to complement blockchains with artificial intelligence (e.g., machine learning) to detect potential specialty logistics issues. Recent industry statistics find that investment and spending on blockchain-based technology have each topped more than US\$1 billion and continues to accelerate. Accenture's current projections for the blockchain services market alone estimates a CAGR of more than 60%, hitting close to US\$7 billion by 2021. Within life sciences alone, blockchain technology could provide a US\$3 billion opportunity by 2025.

Compared to the financial markets as an example, the life sciences industry's participation with the technology remains in its infancy. But Accenture research shows that within the next three years, approximately 30% of life sciences companies plan to utilize blockchain, opening new business opportunities and addressing challenges of the past.



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In Brief (cont.)...

serving the life sciences, but also indicates how the business has evolved to meet the industry's need for a best-in-class and integrated portfolio of commercialization launch and in-market solutions.

- ♦ U.S. pharmaceutical manufacturer **Allergan** reported third quarter results for fiscal 2018 and raised its revenue guidance US\$15.58 billion to US\$15.73 billion, going forward for 2018. The company reported a loss of US\$37.9 million (US\$.11 per share), reflecting a 3% decline in net revenue, largely due to a loss of patent protection on some of its brands. The company also realized a 20% decline in its *Restasis* dry eye therapy brand compared with the prior year, mostly due to lower net pricing, demand and trade inventory levels.

- ♦ Chinese vaccine maker **Changsheng** was fined US\$1.15 billion for their involvement in a human rabies vaccine scandal in July 2018. A compensation plan for victims was also unveiled, awarding families of those who died or were disabled or paralyzed a one-time payment. The company was found guilty of falsifying production and inspection records in the making of rabies vaccines.

- ♦ Japan's ethical drug sales declined 2% in August year-over-year, according to a report released by **Crecon Research and Consulting**. On top of the April drug price cut and ongoing shift to generics, the decline was attributed to a decrease in the number of outpatients, as well as a decrease in product promotions by wholesalers, due to a shift in focus to price negotiations. Positively, newly-launched drugs fared strongly, adding to growth of hepatitis C and cancer treatments.

- ♦ **Chugai Pharmaceutical** (Japan) and **Genentech** (both **Roche** companies) filed patent infringement suits against **Daiichi Sankyo** and **Pfizer Japan** in an effort to block the launch of their biosimilar versions of its anti-HER2 monoclonal antibody *Herceptin* (used in the treatment of breast cancer.). In the lawsuits, the companies submitted petitions for provisional disposition orders, and a demand for the suspension of marketing and distribution of the two *Herceptin* biosimilars, which were approved last month and are expected to launch as early as November.

- ♦ **CVS Health's MinuteClinic** launched its telehealth visits in seven more states, bringing the total to 17, including the District of Columbia. "At CVS Health, we are committed to delivering high-quality care when and where our patients need it and at prices they can afford. This new MinuteClinic service offers even more patients access to an innovative, on-demand health care option right from their cell phone," said *Marc-David Munk*, CVS Health MinuteClinic's chief medical officer. The company has been working with *Teladoc*, leveraging *Teladoc's* technology platform which is initiated through the CVS Pharmacy app.

(Sources: *China Daily*, *Company Press Releases*, *CBS Marketwatch*, *Drug Store News*, *MENAFN.COM*, and *Pharma Japan*)