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IFPW Service Member Spotlight

IFPW Welcomes GLOBALRx as its Newest IFPW Service Member

GLOBALRx, based in the U.S., is a licensed wholesale distributor, pharmaceutical exporter, and GDP-compliant company dedicated in its mission to provide approved medications to individuals, hospitals, pharmacies and specialty wholesalers at the lowest cost possible in countries where those drugs are not readily available. GLOBALRx's inception began with a Wall Street Journal article published in early summer of 1996. The article described the difficulties that patients living outside of the United States were experience in trying to access the few drugs for AIDS on the market at that time. These drugs were available in the United States but limited in availability elsewhere around the world.

GLOBALRx's philosophy is rooted in its belief that patients deserve to be treated with the best available medication irrespective of the country in which they live, or their social or economic status, as sickness is not an issue where politics has any role.

An insightful group of pharmacists viewed this as a chance to meet an obvious pharmaceutical need as well as a timely business opportunity. Initially, these drugs to treat AIDS (later to be called HIV) were provided on a named-patient basis. Subsequently larger quantities of both AIDS drugs and others not available outside of the United States were requested by specialty importers overseas. By 1998, the majority of orders received by GLOBALRx came from the specialty importers as opposed to patients or their physicians. This remains the case today, although GLOBALRx continues to provide prescription drugs on a named-patient basis.

The company employs a full-time compliance department as well as pharmacy staff and a rigorous quality management system. To minimize diversion, GLOBALRx follows a strict vendor and client vetting procedure, and provides full traceability of pharmaceuticals back to the manufacturer.

Sales in 2018 exceeded US$10 million, and included both branded and generic drugs. These drugs were provided to patients in over 20 countries from GLOBALRx's US-based headquarters and distribution facility in North Carolina.

GLOBALRx is proud to be a member of IFPW and looks forward to becoming an active participant in the international effort to prevent diversion of drugs in the international pharmaceutical market, while increasing the availability of these important medicines to patients around the world.

For more information on GLOBALRx and its valuable services, please visit *www.GLOBALRx.com*.

For more information on how to your organization can become a member of IFPW, please contact Christina Tucker at c.tucker@ifpw.com

In Brief...

- **Biologics by McKesson** entered into an exclusive distribution agreement with **Sanofi Genzyme** as the exclusive pharmacy provider of *CABLIVI (caplacizumab)* as well as therapies for six other complex oncology conditions. Biologics by McKesson has recently made significant investments to leverage more than 25 years of oncology experience. *CABLIVI* was approved on February 6, 2019 by the U.S. FDA for use in the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (TTP), a rare life-threatening blood disorder. It is used in conjunction with plasma and immunosuppressive therapy for the treatment of adults with TTP. Biologics by McKesson is an independent specialty pharmacy with extensive experience in connecting patients to life-changing medications in oncology and other therapeutic areas. Separately, **McKesson Corporation** announced a collaboration with technology company **Navigating Cancer** to offer an enhanced *Patient Relationship Management (PRM)* platform for community-based oncologists. The platform is a comprehensive clinical workflow tool for oncology teams providing integrated and personalized care and capturing patient-reported outcomes and symptom management pathways.
- **Walgreens Boots Alliance** (WBA) has named *Heather Dixon* as senior vice president, global controller and chief accounting officer effective March 18th. She leaves behind her position of vice president, controller and chief accounting officer at Aetna, as well as similar positions at PepsiCo. and American Express. She will report to *James Kehoe*, executive vice president and global chief financial officer for WBA.
- **AmerisourceBergen's** patient support service company, **Lash Group**, announced a partnership with **AllazoHealth**, an artificial intelligence and predictive analytics company

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Big Brands Look to Lose Exclusivity to Generics in 2019 as Biosimilars are Expected to Increase Presence

(Source: An Article by Jessica Merrill for Scrip)

Several high-profile blockbuster drugs will likely lose their patent exclusivity in 2019 with launches of generic versions of *Advair (fluticasone/salmeterol)* and *Lyrica (pregabalin)* all imminently expected. "Since the patent cliff, we have had essentially the same US$15 billion-US$17 billion of negative impact from expirees in the U.S., and our modeling suggests that it is supposed to pop this year," Research Director for the IQVIA Institute for Human Data Science, Michael Kleinrock, said in an interview. Conversely, he also pointed to delays in launching, or a slower uptake for certain complex generics and biosimilars.

"You can have a generic approved. It can reach the market, and the originator can rrtain a fairly large share of the volume of

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Big Brands (cont.)...

sales," Keinrock noted. This has been witnessed by some recent entrants into the market such as *Copaxone (glatiramer)* by Teva Pharmaceuticals or Johnson & Johnson's *Remicade (infliximab)*.

GlaxoSmithKline's *Advair* lost patent protection in 2016 when the drug's device patents expired. However, getting a generic version of the drug approved by the FDA proved challenging due to the complex nature of the drug. Eventually, Mylan was victorious and launched its generic version, *Wixela Inhub* in February undercutting GSK's *Advair* list price by 70%. As of March 1, Mylan commanded 24% of prescription drug market share. Mylan's generic version has faced some challenges but has made a relatively strong showing in a short amount of time.

Another drug facing generic competition is Amgen's *Sensipar (cinacalcet)* which is used in the treatment of secondary hyperthyroidism in chronic kidney disease patients on dialysis, as well as hypercalcemia in patients with parathyroid carcinoma. The composition of matter patent expired in March of 2018, but Amgen continues to defend a formulation patent which does not expire until September of 2026. Teva launched a generic version for a brief time but stopped selling the generic version after a patent settlement with Amgen (which is now under scrutiny for antitrust questions.) Since then, generic versions of *Sensipar* have been launch by both Cipla Ltd. and Piramal Enterprises Ltd. despite ongoing court battles. Uncertainty remains as we wait to see how the litigation plays out.

Pfizer Inc. is forecasting challenges in 2019 surrounding their pain drug *Lyrica*, its number two seller, as it loses patent exclusivity beginning June 30th. (Pfizer already received a six-month extension from the FDA for pediatric use.) Other companies, such as Allergan Inc., prepare for the impact of the launch of generic versions of its blockbuster dry eye drug, *Restasis (cyclosporine ophthalmic emulsion)*, its second-bestselling drug after *Botox*. In 2017, a U.S. district court invalidated four patents covering Restasis, a ruling which was held up on appeal in November of 2018. Both Teva and Mylan will launch generic versions of *Restasis* in the near future, since Allergan only maintains exclusivity through March 31, 2019.

Meanwhile 2019 is also poised to be particularly notable for biosimilar launches, including biosimilars in direct competition with Roche's cancer drugs like *Herceptin (trastuzumab)*, *Rituxan (rituximab)* and *Avastin (bevacizumab)*. While the exact timelines for these launches is not known, the U.S. Food and Drug Administration has approved biosimilars for all three drugs, subject to patent settlement agreements and ongoing legal disputes. Roche Pharmaceuticals CEO, William Anderson, said that it is difficult to forecast how biosimilar competition will play out, both in terms of timing and return. "We've baked in some impact in the second half, and it's not a huge impact, because it happens in the second half and there is only so much that can happen," he said.

Biosimilars will make for some interesting observations in the broader U.S. market since they will represent the first wave of monoclonal antibody biosimilars for cancer. This could bring on unique commercial dynamics than earlier biosimilar launches. There could be more questions regarding efficacy posed by patients and physicians, but as pointed out by IQVIA's Kleinrock, there could be distinct advantages concerning the physician "buy and bill" model versus pharmacy dispensing. Currently the "buy and bill" model is based on how companies work with the purchasers on the discounts and pricing as they relate to the ASP (average selling price) model under Medicare Part B. Kleinrock said, "There is a way to encourage greater uptake where there is a group purchase decision, say from a cancer center for Herceptin."

While the U.S. biosimilars market is beginning to take shape and become a more significant presence, the introduction of cancer biosimilars presents a greater hurdle, and the effect on the industry's biggest brands with the entrance into the market by these drugs remains to be seen.

In Brief (cont.)...

specifically focused on patient outcomes. The partnership will enhance patient adherence and engagement programs through targeted and personalized recommendations that will empower at-risk patients to make healthier choices. Studies show medication nonadherence can be caused by both situational and behavioral barriers unique to each patient through the use of AllazoHealth's proprietary AllazoEngine. Lash Group will be the first HUB services provider to leverage individualized patient predicted risk combined with machine learning to provide personalized interventions unique to each patient.

- A new study by **Cardinal Health** shows that more than 50% of hospital executives reported that healthcare industry pressures, as well as the lack of time and resources, prohibit them from focusing on innovative initiatives for their hospital. More than two-thirds of respondents revealed that they don't even consider innovation that could be leveraged within the hospital pharmacy. Additionally, despite expectations of these hospital leaders to drive improvements, these leaders indicated that 50% of all pharmacy-related improvements were the result of reactionary – not proactive – decisions that could directly improve efficiency and the bottom line.
- Pharmaceutical manufacturer **Merck** and **NGM Biopharmaceuticals Inc.** (NGM) announced that Merck has exercised its option to extend the research phase of the companies' broad, strategic collaboration for an additional two years to March of 2022. This collaboration focuses on discovering, developing and commercializing novel biologic therapies across a varied range of therapeutic areas. Merck retains one additional extension option to march of 2021. Separately, **Merck KGaA** will invest US$1.13 billion in its headquarters based in Darmstadt, Germany. The company signed a comprehensive agreement with the Joint Works Council at Darmstadt covering the 11,000 employees to secure its "future viability."
- Italy and China have signed a memorandum of understanding in support of Beijing's "Belt and Road" initiative aimed to weave a network of ports, bridges and power plants linking China with Africa, Europe and beyond. The memorandum makes Italy the first of the Group of Seven major economies, which includes the United States, to join the Belt and Road. This follows Portugal's embrace of the initiative in December. Part of the motivation behind Italy's decision appears to be the hope that it will drive Chinese investment in Italy's ports which in turn would bring a revitalization to Italy's role as a key link between the East and the West. This will also give China a crucial inroad into Western Europe and a symbolic economic boost in its ongoing issues with the United States.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Scrip and The Washington Post)