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IFPW Members "Delivering Health to the World"

(Sources: IMS Institute and the Center for Healthcare Supply Chain Research)

New research published by the Center for Healthcare Supply Chain Research, HDMA's research foundation, indicated that pharmaceutical distributors provide the specialty pharmaceutical supply chain essential services while efficiently aggregating and delivering thousands of lifesaving medications to a large network of providers for the treatment of critically ill patient populations with chronic or rare diseases.

Conducted by PwC Strategy, formerly Booz & Company, the research found that the distributors' significant investments in value-added services in areas of decision support tools, analysis and reports, consulting and patient service categories provide direct savings to the healthcare industry. For example, a subset of the support services provided to physician's clinics represent approximately US$1 billion in economic savings to the healthcare sector. These services include automated and integrated billing and receivable management systems, workforce management tools, revenue cycle and reimbursement services, as well as offerings to enhance the patient experience. Although these types of services vary from market to market worldwide the principal role of pharmaceutical distributors, in efficiently and economically delivering essential medicines to patients throughout the world, does not.

Additional findings of the report state that specialty medicines continue to represent a large and quickly increasing share of prescription drugs in the U.S. - these medicines are expected to represent 43% of the market share by 2020; About 90% of all specialty drug sales revenue flows through traditional and specialty distributors; Changing industry dynamics, including market consolidation and shifting alliances, the evolving regulatory environment, the introduction of biosimilars and the shift to providing value-based care to patients, are creating challenges and opportunities for trading partners in this segment.

As reported earlier and indicated in the above findings, the global pharmaceutical market is rapidly changing with cost efficiency and access being paramount. IMS reports that globally the use of medicines will reach 4.5 trillion doses by 2020 costing US$1.4 trillion. The largest pharmaceutical-using countries will be the pharmerging markets, accounting for two-thirds of the global medicine volumes, mostly comprised of generic medicines and reflecting dramatic increases in utilization of medicines due to broad-based health system expansions. Medicines in 2020 will include a vast array of treatments ranging from those that provide symptom relief available without a prescription to lifesaving genetically personalized therapies unique to a single patient. Disease treatments in 2020 will be transformed by the increased number and quality of new medicines in clusters of innovation around cancer, Hepatitis C, autoimmune disorders, heart disease and an array of rare diseases. By 2020, technology will be enabling more rapid changes to treatment protocols, increasing patient engagement and accountability, shifting patient-provider interaction, and accelerating the adoption of behavior changes that will improve patient adherence to treatments. Pharmaceutical distributors/wholesalers will be in the center of this expansion, delivering health to the world.

In Brief . . .

- The **PHOENIX group's** total operating performance, including revenue and handled volume for services charge, rose 5.2% to €21.2 billion/US$23 billion for the 9 months ended October 31st. Revenue rose by 3.9% in the period to €17.4 billion/US$18.9 billion, driven by an increase in revenue in Germany where the pharmaceutical wholesale market experienced considerable growth. EBITDA rose 2.4% to €340.1 million / US$370 million in the 3 quarters.
- **Walgreens Boots Alliance** reported fiscal first-quarter earnings of US$1.11 billion, USD$1.03 on an adjusted EPS basis, on revenues of US$29.03 billion. "The year has started with a comparatively strong first quarter, as we expected," CEO *Stefano Pessina* said in a statement. "Our ongoing work to control costs across Walgreens Boots Alliance and improve adjusted operating income margins is growing earnings overall. Although it is early in the year, we are on track to deliver against our expectations." Separately, the company reiterated that their deal to acquire US pharmacy chain Rite Aid is progressing as planned.
- **AstraZeneca** has agreed to acquire a majority stake in **Acerta Pharma**, a privately-held cancer drug developer with operations in the Netherlands and in California, for US$4 billion. The deal gives AstraZeneca the option to buy the remainder of the company for US$3 billion and will further bolster its line of cancer treatments.
- **Bayer AG** (Germany) announced the completion of **Panasonic Healthcare's** acquisition of Bayer's **Diabetes Care** business. The total consideration for the transaction is approximately €1.0 billion/US$1.08 billion. The acquired Diabetes Care business will operate as a stand-alone company to be named **Ascensia Diabetes Care**.
- In a December 21st meeting Japanese health and finance ministers agreed on the revision rates of medical reimbursement fees and drug prices for next April, paving the way for an effective price reduction of 7.8%, on drug price decreases of 1.22%. In what was referred to as "a quota outside revision rates," the ministers also agreed to reduce drug prices within central government drug spending, which accounts for approximately one-fourth of Japan's medical expenditures, by another ¥50 billion/US$424 million through a variety of measures.
- Novel drug approvals in the U.S. have reached a 19-year high, as the industry continued to hone its R&D focus on treatments for orphan diseases and personalized medicine. In 2015, 45 new medicines were approved by the **US Food and Drug Administration**, exceeding the 2014 figure of 41, a record since

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A New Pharmacy Model Emerging?

(Sources: an article prepared by Tracy Staton published by FiercePharma and the Wall Street Journal)

Valeant Pharmaceuticals' much talked about agreement with Walgreens includes an unusual inventory provision that helps explain why the pharmacy chain might have been eager to strike a deal. As The Wall Street Journal reports, Valeant is buying back its drugs from Walgreens and selling them on consignment to the pharmacy, a provision that triggers an upfront financial hit for Valeant. Walgreens won't physically return the drugs, just the title to them, a source close to the deal told the newspaper. It's just one out of the ordinary feature of an unusual pharmacy deal.

Valeant announced that it had teamed up with Walgreens to distribute its drugs, discounting key skin and eye brands by 10% and another list of drugs by an average of 50%. Walgreens is taking the Valeant drugs on consignment and collects fees for filling prescriptions, the newspaper says. In fact, one analyst told the Journal, the drugstore chain may earn more from those fees than it would via the usual method of buying at wholesale and filing for insurance reimbursements.

Valeant said the Walgreens deal would cut revenue by US$150 million, which includes the cost of shifting its drugs to consignment status, expected delays in recognizing revenue from the partnership and reduced sales to wholesalers that had been selling Valeant meds to Walgreens, the WSJ reports.

The Walgreens partnership replaces Valeant's relationship with Philidor, a specialty pharmacy that was closely tied to the drug maker until questions arose about its operations. The drug maker is expecting a sales hit from the pharmacy shift, partly because of the mechanics of the Walgreens deal and partly because of lower demand for its drugs in the wake of the Philidor allegations. The company cut its Q4 revenue outlook to US$2.7 - US$2.8 billion from US$3.25 - US$3.45 billion.

Valeant's image is also suffering as increased scrutiny on drug prices has put an unwelcome spotlight on some of company's recent price increases and its light R&D business model.

U.S. Specialty Market

(Source: Barclay's Equity Research Report, "Specialty Market Model 2016 Update", dated 6 January 2016)

From the perspective of pharmaceutical supply chain participants – chiefly distributors, pharmacy benefit managers (PBMs) and pharmacies – the specialty marketplace is composed of several distinct but interrelated channels, including specialty pharmacy, specialty distribution and specialty manufacturer services. The above referenced report provides a channel-specific view of the specialty pharmaceutical market, differentiating between specialty pharmacy and specialty distribution markets and growth opportunities.

Specialty Market. Barclay sizes the total U.S. specialty pharma market at US$178 billion in 2015, of which US$100 billion flows through the specialty pharmacy channel dominated by the chain drugstore operations of CVS and Walgreen Boots Alliance (WBA), the PBM, Express Scripts (ESRX), and to a lesser extent Diplomat, OptumRx and Cardinal Health (CAH). US$78 billion flows through the specialty distribution channel, dominated by AmerisourceBergen (ABC), McKesson (MCK) and CAH. Barclay projects total specialty expenditures will expand to US$282 billion in 2020, a five-year representing a CAGR of 10%.

Specialty Pharmacy (SP). The rate of SP market growth is poised to decrease to a 7% CAGR in 2015-20 from a 16% CAGR 2010-15, as the Hep C (hepatitis C) class expanded by US$12 billion in 2014 and 2015 but will contract by US$7 billion 2015-2020. Despite the decline in Hep C, Barclay projects the SP market will grow by US$42 billion, from US$100 billion in 2015 to US$142 billion in 2020, on strength in oncology, rheumatic diseases, respiratory and the new PCSK9 category (a new class of drugs that have been shown to dramatically lower LDL cholesterol levels). Barclay believes pure-play Diplomat Pharmacy Inc. (DPLO) has the greatest leverage to SP market growth, PBM ESRX has the greatest leverage to total specialty growth (via SP and increasing formulary management), and integrated PBM/Retailer CVS is poised to capture both dynamics while also leveraging its large infusion footprint and retail touch points.

Specialty Distribution (SD). The rate of SD market growth will increase to 12% from 10%. Barclay projects the SD market will grow by US$62 billion, from US$78 billion in 2015 to US$140 billion in 2020, on strong growth in oncology, musculoskeletal, ophthalmology, and cardiology as well as large contributions from vaccines, ophthalmology and rheumatology. While the growth outlook is steady, Barclay believes the competitive outlook for distributors has improved as the shift from the community oncology to hospital outpatient setting that weighed on distributor growth in 2013 and 2014 stabilized in 2015. ABC maintains the largest and most diverse specialty operation (including both SD and manufacturer services) but no longer has significantly greater earnings leverage from SD as compared to its distribution peers. MCK's strength in oncology positions it well relative to the pipeline for new infused products and potentially biosimilars. Cardinal expanded its specialty distribution position in 2015 and is developing an interesting manufacturer service offer but remains considerably smaller than its peers.

In Brief (cont.) . . .

1996. Also, for the 2nd consecutive year the regulator cleared a record number of rare disease therapies, which accounted for more than 40% of the new approvals.

- **Shire** is reportedly in advanced talks to acquire **Baxter's** biopharma spin-off **Baxalta**. Sources familiar with the deal have said that the Irish firm could buy Baxalta for US$32 billion, including a cash component. *Flemming Ornskov*, CEO of Shire, has said the companies could deliver US$20 billion in product sales by 2020.
- The Indian pharmaceutical industry is expected to reach US$55 billion by 2020 as against the current size of US$18 billion, but exports may slow down to a 7.98% growth rate, in value terms, due to tightening of regulatory mechanisms in the top export markets of US, Russia and Africa.

(BusinessWire, CNBC, New York Times, PharmaJapan, PharmaTimes, PHOENIX group, Walgreens Boots Alliance)