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Specialty Pharmaceuticals

(Source: edited excerpts from an article prepared by David Salazar and published by Drug Store News, IMS Health & Wikipedia)

It wasn't too many years ago when Biotech pharmaceuticals evolved into a new category called Specialty Pharmaceuticals. So let's begin with defining Biotechnology in accordance with UN Conventions and Specialty Pharmaceuticals according to Wikipedia.

Biotechnology is the use of living systems and organisms to develop or make products, or "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use" (UN Convention on Biological Diversity, Art. 2).

Specialty drugs or specialty pharmaceuticals are a recent designation of pharmaceuticals that are classified as high-cost, high complexity and/or high touch. Specialty drugs are often biologics, "drugs derived from living cells" that are injectable or infused (although some are oral medications). They are used to treat complex or rare chronic conditions such as cancer, rheumatoid arthritis, hemophilia, H.I.V., psoriasis, inflammatory bowel disease (IBD) and Hepatitis C.

In 1990 there were 10 specialty drugs on the market, in the mid-1990s there were fewer than 30, by 2008 there were 200, and by 2015 there were 300. Drugs are often defined as specialty because their price is much higher than that of non-specialty drugs. The U.S. government program, Medicare, defines any drug for which the negotiated price is US$600 per month or more, as a specialty drug which is placed in a specialty tier that requires a higher patient cost sharing.

Drugs are also identified as specialty when there is a special handling requirement or the drug is only available via a limited distribution network. By 2015 "specialty medications accounted for one-third of all spending on drugs in the United States, up from 19 percent in 2004 and heading toward 50 percent in the next 10 years," according to IMS Health, which tracks prescriptions. According to a 2010 article in Forbes, specialty drugs for rare diseases became more expensive "than anyone imagined" and their success came "at a time when the traditional drug business of selling medicines to the masses" was "in decline." A 2015 analysis by The Wall Street Journal suggested the large premium was due to the perceived value of rare disease treatments which usually are very expensive when compared to treatments for more common diseases.

Accordingly, it's no secret that the category of drugs drawing the most attention — and money — in recent years has been specialty pharmacy. Therefore, it shouldn't be surprising that the growth the category has experienced in the past several years — pushed more recently by hepatitis C and oncology treatments — isn't expected to slow anytime soon.

Specialty pharmacy sales growth for the year ended September 2015 rose by 23%, according to IMS Health — far outstripping the 8% sales growth that traditional medicines saw during the same period. This increase in sales is accompanied not just by growth in the amount of healthcare spend, but also by an uptick in the regulatory approval of novel new drugs — a group that is about half composed of products dispensed through specialty pharmacy — in the past several years.

In 2014, the Food and Drug Administration set a record when it approved 41 novel new drugs, in addition to 19 new biologics. But in 2015, the agency surpassed its own record, approving 45 novel new drugs and nine biologics. As Diplomat Pharmacy pointed out in its report on the state of specialty pharmacy, many of the novel new drugs and biologics also receive special

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In Brief . . .

- **Cardinal Health** reported a 21% increase in revenue to US$30.7 billion for its fiscal 3rd quarter. Pharmaceutical segment revenues increased 22% in the period to US$27.5 billion (due to growth from new and existing customers as well as acquisitions) while revenue for the Medical segment increased 13% to US$3.1 billion. "We had a strong financial and operational performance in our fiscal third quarter. At the same time, we continued to enhance and grow enterprise-wide service and product lines, which are important to our customers and address some of health care's most difficult challenges," stated *George Barrett*, chairman and CEO Cardinal Health.
- **McKesson**, through its **McKesson Business Performance Services** unit, has partnered with **Blue Cross Blue Shield of Arizona** (BCBSAZ) to form a joint venture designed to deliver a broad range of services to help healthcare providers succeed in today's value-based environment. The new company, **ACO Partner**, is being called a *Maximum Services Organization*, and will be an innovative collaborative that will leverage McKesson's physician engagement, care management, and population health services and technology. ACO Partner plans to contract with payers and provider groups nationwide to increase the overall quality of care through strong partnerships in pursuit of the triple aim of lowering costs, improving outcomes and enhancing overall patient experience.
- **Quintiles** and **IMS Health** are planning to merge, to create a new clinical services and analytics powerhouse, in all-stock transaction valued at nearly US$9 billion. The combined entity to be called **Quintiles IMS** with annual revenues of more than US$7 billion, will offer a distinctive global real-world evidence solutions platform underpinned by "a leading portfolio" of anonymous patient records, technology-enabled data collection and observational research experts, to help address critical healthcare issues of cost, value and patient outcomes. The companies say the move will improve clinical trial design, recruitment and execution in the US$100 billion biopharma product development market by combining IMS Health's global information solutions with Quintiles' product development skills.

(Sources: Business Wire, Drug Store News and Pharma Times)

Specialty Pharmaceuticals (cont.) . . .

designations from the U.S. FDA, including orphan designation, fast track, accelerated approval and priority. These designations might be contributing to the boom in specialty drug applications and a focus on their development by manufacturers, according to an "emerging therapeutics" analyst.

"There are a lot of specialty drugs in the late-stage pipeline right now," stated the analyst. "I think a lot of it has to do with some of the FDA special designations that are out there helping to move drugs through the development process and the FDA review process more quickly than we used to see. ... The FDA has a history of granting approvals for drugs treating disease states where there are few or no currently available treatments."

One disease state that several years ago had few treatments, but now is one of the main classes of specialty drugs are treatments for hepatitis C. The big news of 2014 was the approval of *Harvoni*, which in many cases cured a patient's viral hepatitis. In 2015, Harvoni received a new indication by the FDA, as did *Technivie*, to treat different genotypes of hepatitis C. Last year also saw the approval of *Deklinza*, which treats genotype 3 hepatitis C infection. And though the last several years in specialty have been focused on hepatitis, it's possible another class of drugs will soon be driving growth.

The analyst expects that the first likely treatment for nonalcoholic steatohepatitis or NASH — fatty liver disease among patients who don't have a history of alcoholism — will be approved this year, but for a different illness — primary biliary cirrhosis. As a result, the first drug indicated to treat NASH could launch in 2017. Beside NASH treatments, the analyst noted that PCSK9 inhibitors also could be poised for growth. [PCSK9 is an enzyme encoded by the PCSK9 gene in humans. PCSK9 binds to the receptor for low-density lipoprotein (LDL) cholesterol. In the liver, the LDL receptor removes LDL cholesterol from the blood. When PCSK9 binds to the LDL receptor, the receptor is broken down and can no longer remove LDL cholesterol from the blood.]

AstraZeneca to 'Reshape' Manufacturing as Part of US$1.5B Cost Cutting Effort

(Source: Edited excerpts from an article prepared by Eric Sagonowsky and published by FiercePharma)

AstraZeneca executives introduced a plan to save US$1.1 billion annually as the company's top drug, *Crestor*, loses patent protection, making vulnerable about US$5 billion in annual sales. In response, AstraZeneca has developed a restructuring that will cost about US$1.5 billion – a one-time expense mostly cash - and includes a move to "reshape our manufacturing base," CFO Marc Dunoyer told investors.

AstraZeneca CEO Pascal Soriot explained on an investor call that the effort will "streamline the operations, primarily in commercial and manufacturing," in order to "deliver a material decline in our core SG&A cost in 2016 and 2017." Dunoyer added that AstraZeneca will strive to "make far greater use of shared services" while "optimizing our presence in key strategic sites."

The news comes following AstraZeneca's announcements toward the end of 2014 that it would shutter two plants, one each in the U.S. and U.K. In December 2014, it said by the end of 2015 it would close a plant in Westborough, MA, and by 2016 or 2017, it would shutter an API site in Bristol, U.K., following patent losses. The Bristol plant makes the active pharmaceutical ingredients (API) for Crestor and a couple of other drugs, while the U.S. plant manufactured AstraZeneca's respiratory drug *Pulmicort Respules*, which is slated to go off patent in 2018.

However, the company has also showed an eagerness to strengthen its biologics manufacturing, with Dunoyer saying that the new cost drive will take "into account the need to create capacity in our biologics supply chain." His sentiment follows several previous moves by AstraZeneca in that direction. Back in 2014, the company said it would invest US$200 million in a biologics plant in Frederick, MD, bolstering capacity and adding about 300 jobs when the work is complete in 2017. Then last May, AZ said it would build a US$285 million biologics plant in Sweden that should be ready by 2018 to grow new launch capacity. In September it bought a biologics plant in Colorado from Amgen following that company's layoff drive.

Though some details remain unclear on just which jobs and operations will be impacted with this restructuring, AstraZeneca is far from alone in seeing the need to shake things up following a major patent loss. Big Pharma peers such as Sanofi, Novartis, Merck, GlaxoSmithKline and others have all had to rely on the tactic in recent years following patent expirations. Sanofi, for one, is in the process of a US$1.6 billion cost cutting drive that may affect manufacturing and vaccines. The company set forth earlier this year with plans to cut 500 jobs in France, according to reports. Before that, back in 2014, Teva said it would eliminate half its plants over 5 years to cut costs and increase efficiency. Last August, after having cut more than 36,000 jobs in the previous 5 years, Merck said about 2,585 cuts remain by the end of 2016, mostly in manufacturing.

IFPW Announces Two New Appointments

IFPW is pleased announce two new appointments effective immediately.

Mr. Eero Hautaniemi, President and CEO of Oriola-KD Corporation (Finland) since 2006, will join IFPW's Board of Directors as a Regional Director for the EMEA region. Mr. Hautaniemi has also served as President of GE Healthcare Finland Oy during 2004–2005, and as General Manager and Vice President of Oximetry, Supplies and Accessories business area of GE Healthcare IT in 2003–2004.

Mr. Hautaniemi is a member of the Board of Directors of Lassila & Tikanoja Corporation, and of the Board of Finnish Commerce, as well as a member of the the GIRP Management Board.

IFPW would also like to announce the appointment of Mr. Jean-Marc Leccia to the IFPW Foundation's Board of Trustees.

Mr. Leccia is Chairman and CEO of Eurapharma (France). He began his career at Baxter Laboratories in charge of exports for the Maghreb region in Africa and joined Eurapharma in 1991 where he was responsible for promotional activities. In 2000, he created Epdis France's pre-wholesale activity. Mr. Leccia has also been the Head of English-and Portuguese-speaking Africa and the Maghreb since 2005.

IFPW is pleased to have Mr. Hautaniemi and Mr. Leccia serve in these roles, and grateful for their knowledge and expertise that they bring with them.