

Overview

- The Academy of Managed Care Pharmacy (AMCP) in its 2013 publication defined specialty pharmacy as the following¹:

“Specialty pharmacies are distinct from traditional pharmacies in coordinating many aspects of patient care and disease management. They are designed to efficiently deliver medications with specialized handling, storage, and distribution requirements with standardized processes that permit economies of scale. Specialty pharmacies are also designed to improve clinical and economic outcomes for patients with complex, often chronic and rare conditions, with close contact and management by clinicians. Health care professionals employed by specialty pharmacies provide patient education, help ensure appropriate medication use, promote adherence, and attempt to avoid unnecessary costs. Other support systems coordinate sharing of information among clinicians treating patients and help patients locate resources to provide financial assistance with out of pocket expenditures.”

- Specialty pharmacy focuses on high cost, high touch medication therapy for patients with complex disease states. Medications in specialty pharmacy range from oral to cutting edge injectable and biologic products. The disease states treated range from cancer, multiple sclerosis and rheumatoid arthritis to rare genetic conditions
- A specialty pharmacist may work in a variety of practice settings. Some pharmacists in this practice area work in pharmacies dedicated to only products that are considered specialty medications. In this setting, pharmacists may work in a variety of areas including dispensing, medication therapy management, patient advocacy and therapy compliance. Some pharmacists work in institutional or health system settings and may be involved with the patient’s therapy from in-patient to ambulatory care sites
- Other pharmacists work in more traditional retail settings and either focus on certain specialty disease states at their practice sites or work with an affiliated specialty pharmacy provider to dispense these complex medications²

Specialty Drug spending is expected to more than XXXX by 2020, reaching about \$XXXXB a year. Fewer than X% of patients use specialty medications, but they account for XX% of healthcare costs

Source: XXXX XXXX Paper on Specialty Drugs

Specialty Drug

- Specialty Pharmacies are most often focused on the dispensation of specialty drugs. While there is no standardized definition of what constitutes a specialty drug, most often they meet the following criteria:
 - The drug is a **specialized, high cost product** (typically more than \$XXX per month)
 - The drug is **utilized as a complex therapy** for a complex disease
 - The drug requires **special handling or administering, shipping, or storage**
 - The drug **may have a FDA Risk Evaluation and Mitigation Strategy (REMS)** in place specifying that there is required training, certifications, or other requirements that must be met in order for the drug to be administered
 - The drug has the **potential for significant waste due to high cost**

¹ XXXX

² XXXX

- Because of the specialized way in which these drugs need to be administered, specialty pharmacies come into play with a specific focus on this group of drugs and the required comprehensive and coordinated delivery and support required to effectively deliver these drugs to patients³
- In 1990, XX specialty drugs were on the market. In 2012, over XXX specialty drugs were in development
- Physician-administered drugs are typically dispensed by specialty distributors and sent to physician offices in bulk
- Once administered, the insurance company is billed under the medical benefit, making tracking more difficult as payment does not correlate with the pharmacy benefit
- Historically this category of medication focused on injectable and infused drugs, however significant number of oral dosage forms have entered the market recently with the trend expected to grow⁴

In 2018, XXX of the 10 best-selling drugs by revenue are projected to be specialty drugs, compared with XXX in 2010.

Source: XXXX XXXX Paper on Specialty Drugs

Market Outlook

- By 2018–2020, XX% of all drugs sold in the US are expected to be specialty pharmaceuticals, compared with XX% in 2013
- The business, by one estimate grew to \$XXX in sales in 2014 from \$XXX in 2005⁵ and the specialty market (2013: \$XXXX) is projected to grow over XX% per year which presents financial challenges as well as opportunities. Moreover, it is estimated that five of the largest specialty drug manufacturers will control XX% of the market
- With restrictive contracting from some payers and specialty drug manufacturers, health systems are susceptible to fragmented care of their most vulnerable patients⁶
- For the first time in 2010, the FDA granted more specialty drug approvals than those for traditional drugs. This trend has been continuing year on year, and in 2014, XX of the 51 drugs approved by the FDA were classified as specialty
- Specialty drugs commanded XX% of the total prescription drug spending in 2014, yet only X% of all prescriptions written were for specialty drug. Furthermore, the growth rate in spending for traditional medications was a meagre XX% in 2014, while spending on specialty drugs grew by over XX%, even though only XX% of the commercial population actually uses them⁷

³ XXXX

⁴ XXXX Report

⁵ XXXX

⁶ XXXX

⁷ XXXX

Image About Prescription Drug Spending- Speciality Drugs & Traditional Drugs

Rise of the Specialty Pharma Model⁸

- The sudden rise of specialty pharma companies over the last several years can be partially attributed to several major shifts in the dynamics of the pharmaceutical market:
 1. Big pharma, generally defined as large cap pharmaceuticals, has been grappling with productivity issues. Though R&D investments have doubled over the last decade, new molecular entity approvals have sharply declined
 2. The looming patent cliffs and intense competition from generics companies. It was becoming evident that the vertically-integrated business model, wherein big pharma carries out the entirety of the work from the beginning of product discovery through distribution and marketing, was not providing a sustainable return on investment
- To fill the gap being created, the specialty pharma business model began to establish a foothold within the pharmaceutical market
- As the specialty pharma business model gains popularity and more companies adopt it as their primary business strategy, the characteristics that define what a specialty pharma company is continuing to expand in scope. The term “specialty pharma” is now being used interchangeably with terms such as development-centric pharmaceutical or biopharmaceutical companies
- Some generalizations can be drawn from the specialty pharma business model. **Where big pharma may be involved in developing drugs across five or six therapeutic areas, specialty pharma may initially dedicate resources to only one or two**
- These areas typically have specified physician populations, allowing the companies to downsize their sales forces and shift resources away from traditional marketing and educational strategies to new support programs, tools and mobile solutions that are targeted directly at patients

Drivers

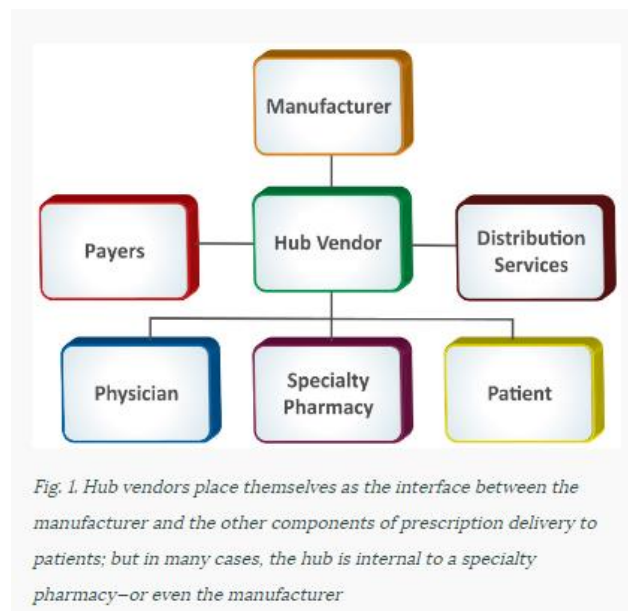
- The key factors driving growth of the US specialty pharmaceutical industry include⁹:
 - **Accelerating US aging population:** The US population is getting older, and with age comes more chronic conditions, diseases and prescription drugs. People with XX+ year of age represented XXX% (XXXX) of the population in the year 2014 but are expected to grow to be XXX% of the population by 2040

⁸ XXXX

⁹ XXXX from World Bank

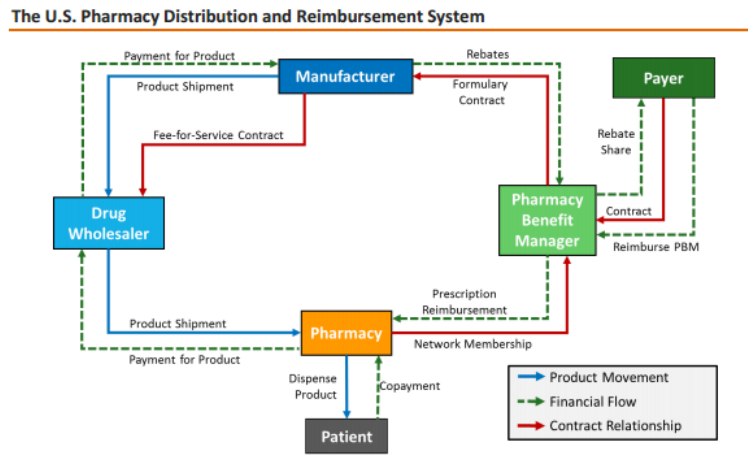
- **Ameliorating economic condition:** The per capital income increased to \$XXXX (2013) from \$XXXX in 2005
- **Increased life expectancy:** Life expectancy in the US has increased from XXX years in 2005 to XXX years in 2013/14
- **Increasing healthcare expenditure:** Although there are a range of possible trajectories for future growth in specialty spending, estimates suggest it could XXXX by 2020, reaching about \$XXXX, or XX% of national health spending
- Currently, specialty drugs are one of the fastest growing segments of the overall pharmaceutical market, as sales growth is being driven by **innovative new drug launches** and the **relatively high cost of therapy** versus traditional drugs
- Specialty pharma companies have small R&D operations and commercial infrastructures, tend to contract out clinical trials and manufacturing to contract research organizations and contract manufacturing organizations, enter strategic partnerships with other healthcare players and develop specialty medicines that are mostly injectable cold chain products

Model



- The above chart¹⁰ gives a brief overview of the specialty pharmaceutical model. The Hub vendor acts as a major intermediary connecting the manufacturer to the end user
- “Hubs” have been around for over a decade, starting out as “reimbursement hubs,” usually provided as a service by manufacturers to help patients and providers navigate the process of obtaining permission to use, and reimbursement for, expensive specialty therapies

¹⁰ XXXX



- The above chart illustrates three key channel flows on Retail, Mail, and Specialty Pharmacies:
- Product movement, which traces bulk distribution from pharmaceutical manufacturers to the drug wholesalers that supply pharmacies. A pharmacy marks the final step in which a prescription is dispensed to a patient
- Financial flows, which transfer money from third-party payers to Pharmacy Benefit Managers (PBMs), who in turn reimburse pharmacies. Funds flow to manufacturers via pharmacies, which purchase drugs from wholesalers. Funds flow from manufacturers in the form of rebates to PBMs, which share a portion of these payments with plan sponsors, reducing net prescription costs. Manufacturers' rebates to PBMs and other third-party payers do not flow through wholesale or retail channels
- Contractual relationships, which govern the relationships between:
 1. Payers and PBMs
 2. PBMs and pharmacies
 3. Pharmacies and wholesalers
 4. Wholesalers and manufacturers
 5. Manufacturers and PBMs

Distribution Model¹¹

Image About The Prescriber-Payer Matrix

¹¹ XXXX

- The above chart depicts the various physical, financial, and transactional factors that manufacturers of specialty pharmaceuticals take into consideration when devising channels through which products can reach the patients
- Though the manufacturers are in control of the flow, payers have significant influence
- However, sometimes the prescribers and payers have no choice because many specialty pharmaceuticals are one-of-a-kind products developed for small patient populations
- Specialty pharmacies typically enter a distribution model for drugs covered under the pharmacy benefit. To mitigate payers' cost fears, specialty pharmacies emphasize programs that promote adherence to therapy and reduce waste

Image about channels leading to dispensing of speciality products under the pharmacy benefit

Image about channels leading to administration of speciality pharmaceuticals under the medical benefit

- Contemporary channels for specialty products can be grouped into two general forms reflecting whether a product is financed under the pharmacy benefit (Figure on left) or the medical benefit (Figure on right). About half of specialty pharmaceuticals are covered under the medical benefit and half under the pharmacy benefit
- Placing a specialty drug under the pharmacy benefit often provides the opportunity for tighter control in real time. Pharmacy benefit managers (PBMs) are trying aggressively to move drugs from the medical to the pharmacy side, or, in some cases, leaving them on the medical side but applying a pharmacy-benefit type of administration. If successful, this strategy will garner new drug volume for the PBMs and improve payers' ability to track utilization
- Some specialty pharmacies are large enough to acquire products directly from the drug manufacturer. Small specialty pharmacies and retail pharmacies that handle specialty pharmaceuticals use the services of a specialty wholesaler. The largest specialty pharmacies are owned by PBMs or large retailers. Whether large or small, specialty pharmacies seek to carve out a niche by offering services that are beyond the capabilities of the typical retail pharmacist, from storage of products to education of patients with rare diseases

Channels¹²

Third-party payers want the distribution of provider-administered specialty drugs to change. In particular, most would prefer that buy-and-bill fade away and be replaced by specialty pharmacy fulfillment. There are two primary channels by which oncology drugs reach the physician office/clinic market:

- **Buy-and-Bill:** After purchasing a drug from a specialty distributor, the provider will store the product at its location. The provider will then administer the specialty drug to a patient. After the patient receives the drug and any other medical care, the provider will submit a claim for reimbursement to a third-party payer. The process is called buy-and-bill, because the medical claim is submitted after the provider has purchased and administered the drug
- **White Bagging:** A specialty pharmacy ships a patient's prescription to the provider, such as a physician office or an outpatient clinic. The provider holds the product until the patient arrives for treatment. The specialty pharmacy adjudicates the claim and collects any copayment from the patient before treatment. With white bagging, there is no buy-and-bill, because the provider does not purchase the drug from a specialty distributor or seek drug reimbursement from a third-party payer. However, the provider will still be paid for professional services associated with drug administration

Image about infused sourcing at oncology practices - Current Channels & Payers Preferred Channels

For specialty distributors, white bagging is a direct competitive challenge, because it diminishes the channel role of specialty distributors. For specialty pharmacies that buy directly from manufacturers, product volume leaves the wholesale distribution channel and moves to the pharmacy channel. If the specialty pharmacy purchases drugs from a full-line wholesaler or specialty distributor, the volume would remain in the channel. However, the distributor would earn less profit from supplying a pharmacy than from supplying a physician office/clinic

Source: XXXX

¹² XXXX

Key Players – Market Share¹³

Image about pharmacy revenues & market share from speciality pharmaceuticals by company in 2015

XXXX, XXXX and XXXX together accounted for more than XX% of the US Specialty Pharma market in 2015.

M&A Deals

Image about M&A deals

¹³ XXXX

