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BioMarketing Insight



Creating markets & marketing
strategies

Newsletter

November 15, 2016

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month I covered "The Real Story Behind the Price of the EpiPen." If you missed last month's article, click [here](#) to read it. This month's newsletter will cover, The Economics of Pharmaceutical Pricing: The Supply Chain.

Read on to learn more about this topic and other current news. The next newsletter will be published on December 15th.

We encourage you to share this newsletter with your colleagues by using the social media icons at the top, or by simply forwarding this newsletter or use the link at the bottom of this newsletter. Should you or your colleagues want to join my mailing list, click on the icon below or scan the QR code.

Please email [me](#), Regina Au, if you have questions, comments or suggestions.

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Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact [me](#) for an appointment. For successful commercial adoption of your product or looking to grow your business, contact [me](#) for an appointment.



For more information on our services, click on the links below:

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What Are the Next Game Changing Drugs in Cancer Therapy?

I am pleased to announce that my article on "What Are the Next Game Changing Drugs in Cancer Therapy?" that covers immuno-oncology drugs (Checkpoint Inhibitors and CAR-T Therapy) has been published in Pharma IQ. To read the article, click [here](#).



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To Cloud Compute, or Not to Cloud Compute?

I am pleased to announce that my article "To Cloud Compute, or Not to Cloud Compute?" on the Pros and Cons of using Cloud Computing and Storage has been published in *Innovations in Pharmaceutical Technology (IPT) Journal*, July 2016, pages 32-35 © Samedan Ltd. To read an electronic version, click [here](#).

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The Economics of Pharmaceutical Pricing: The Supply Chain.

Last month I covered the "The Real Story Behind the Pricing of the EpiPen." In that article, I mentioned that pharmacy retail prices consist of the manufacturer's price plus all the middlemen prices that it takes to get the product from the manufacturer to the customer. This model is the same for consumer products and the customer price will vary just as a bottle of water might cost \$1 in the grocery store, but \$1.75 at a convenience store and \$5 in a hotel room mini-bar.

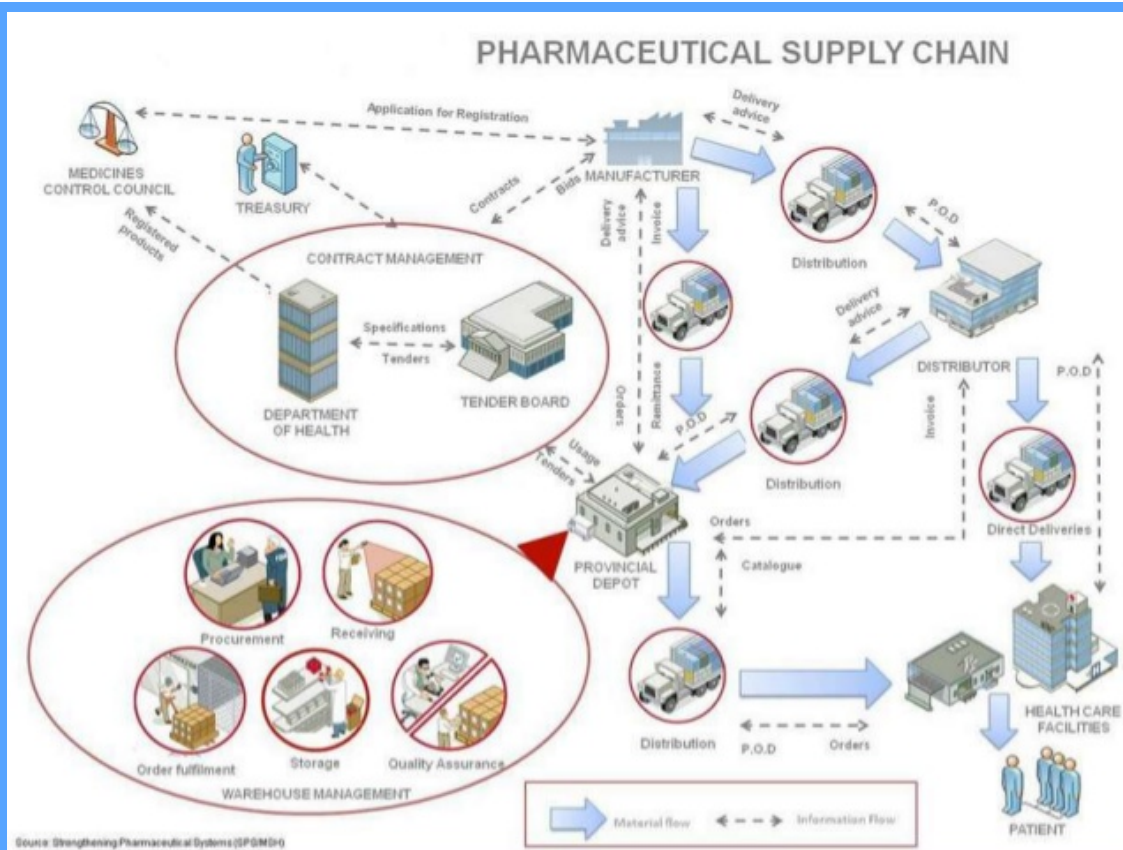
The manufacturer, in this case Mylan, is at the beginning of the supply chain, with their price being 45% of the list price and the middlemen (Pharmacy Benefit Manager, Insurance Company, Wholesalers, and Retail pharmacy) at 55% of list price.

Supply Chain : Retail Cost of EpiPen					
	Middle Men				
	Pharmacy Benefit Manager	Insurance company	Wholesalers	Retail Pharmacy	Customer
Mylan					
\$274/2-pk net sales (45%)	Plus \$334/2- pack (55%)				Equals \$608/2-pk

I've gotten many questions asking why the middlemen account for 55% of the list price, more than the manufacturer's piece of the pie. To help you understand, see this simplified supply chain flow - chart.



However, in order for the product to get into hospitals and pharmacies, a complex process consisting of numerous steps must be followed and by law, every drug must be tracked and accounted for as it passes from one destination to the next, until it reaches the hospital, or retail pharmacies. Liability insurance is also required, in case the integrity of the drug is compromised, or it is stolen. Plus, each major player has its own warehouse inventory management system. See the diagram below.



Let's examine the players more closely:

Pharmaceutical Manufacturers:

Pharmaceutical manufacturers, based on expected demand, manufacturing and distribution costs, future competition and projected marketing costs, establish a wholesale acquisition cost (WAC). This is a baseline price at which wholesale distributors purchase drug products. Discounts and rebates may be applied, based on market share, volume and prompt payment.

Wholesale Distributors:

Wholesale distributors typically sell drugs to pharmacies at WAC plus some negotiated percentage. They may facilitate discounts negotiated between manufacturers and other customers. There has been significant consolidation within the wholesale distribution industry in the last 40 years and the top 3 three wholesale distributors (McKesson, Cardinal Health and AmerisourceBergen) now account for 90% of the wholesale market.

Traditionally, wholesale distributors warehoused product and managed inventory. Today, their role has changed to adapt to the changing

marketplace and now features a number of specialized services, including specialty drug distribution, drug repackaging, electronic order services, reimbursement support and drug buy-back programs. All these services were created in response to increasing pressure to lower costs for the wholesalers.

This major consolidation of the wholesale industry has forced them to change their business model to low-margin enterprise that makes money by maximizing economies of scale, creating operational efficiencies, such as "just-in-time" in the distribution system. This has also made them expand and complement their services with specialty pharmacy and disease management services.

Pharmacies:

Pharmacies complete the pharmaceutical supply chain. They take physical possession of the drug products and are responsible for the drugs' safe storage and dispensing, which includes facilitating billing and payment for consumers participating in group health benefits plans. Pharmacies purchase drugs from wholesalers and occasionally, directly from manufacturers.

Pharmacies serve as an important information link between pharmacy benefits managers (PBMs), drug manufacturers and wholesale distributors. They were the first to be fully automated with electronic billing claim transactions before the industry switched over to electronic medical records (EMRs). Pharmacies generate the prescription drug claims information that PBMs, health plans, employers, governments and other payers rely upon to measure consumer activity. They also play an important role in informing customers and prescribing physicians if a drug is not covered by the patient's health plan (formulary), or if a lower-cost therapeutic alternative is available. In Massachusetts and a number of other states, there is a mandatory substitution for generics, unless the physician writes no substitution, medically necessary and the request is approved by the insurance plan. They charge a fee for their services.

There has also been a major consolidation of pharmacies over the years due to the proliferation of big chains such as CVS and Walmart, that have shoved out the majority of the independents and some of the smaller chains, as well. These mega-chains have significant bargaining power to negotiate lower prices.

There are several types of pharmacies, including independent pharmacies, chain drugstores, pharmacies in supermarkets and other large retail establishments, mail-order pharmacies, long-term care pharmacies and specialty pharmacies, which specialize in the distribution of high-cost and more complex drug therapies (e.g., self-injectable drugs and biologics). Most pharmacies purchase their drug supply from a wholesale distributor, although in some cases, large institutional, retail chain pharmacies and mail-order pharmacies obtain drugs directly from a manufacturer.

Pharmacy Benefit Managers (PBMs):

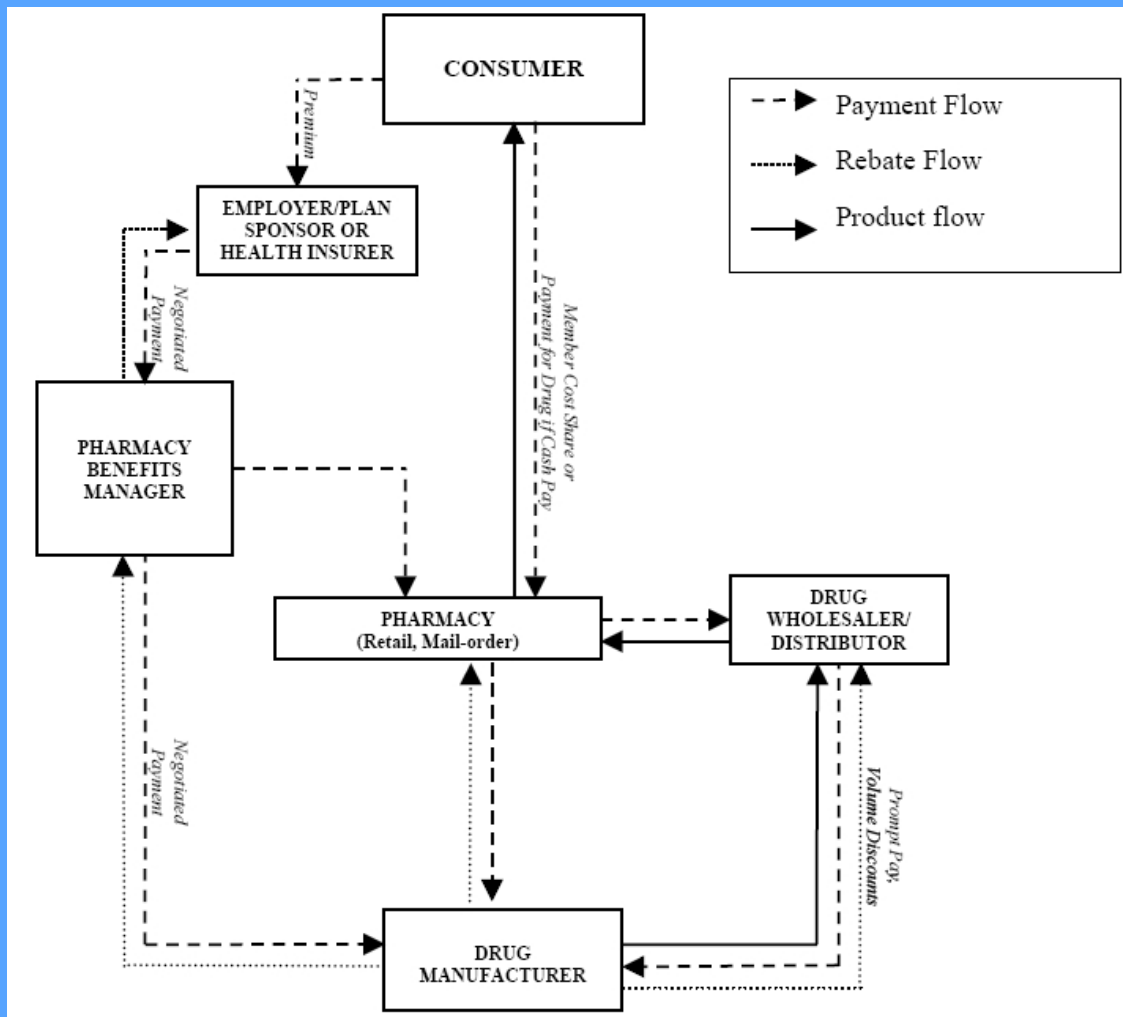
In 2004, it was reported that PBMs (i.e., Express Scripts, Caremark, Medco) manage the prescription drug benefits for 57 % of the U.S. population (Atlantic Information Services Inc.) and probably well over 70 % today. Although the PBMs are not in the physical supply chain for pharmaceutical products, they work with third party payers (private insurers, self-funded employers and public health programs) to manage, negotiate and define which drugs will be paid for and the amounts that the pharmacy will receive; the consumer must pay out-of-pocket when the prescription is filled. They negotiate with manufacturers and pharmacies under regulated guidelines.

Their role has evolved over the last four decades from basic claims administration (claims processing, record keeping, and reporting programs) to providing a wide range of services, including drug utilization review, disease management, consultative services and assisting clients with establishing their benefits structure. These benefits plans include: developing and maintaining a prescription drug formulary; rebates; developing a network of pharmacy providers; and providing mail order fulfillment services, etc. They charge a fee for their services.

The Supply Chain Product, Payment and Rebate Flow:

The way the prescription benefits system was originally set up, since most patients/consumers had insurance, the patients usually paid their co-pay and not the retail price. The insurance companies covered the price of the drug (WAC plus the fees of the players in the supply chain), but that price was rebated back through employer/employee premiums and indirectly through patient deductibles and co-pays along with discounts from the manufacturer, which were negotiated by the insurance company or the PBMs. The diagram below is a simplified version of the rather complex

process and depicts the flow of payments and rebates.



Today, insurance companies refuse to cover the cost of medications and they're passing that cost on to employers through higher premiums (and part of the higher premiums are passed to the employees), and through deductibles and co-pays, which are paid to the pharmacy in lieu of the insurance company paying the pharmacy, or the drug is not covered at all.

This is the reason we are hearing outcry from the public, because there are more and more out-of-pocket expenses for the patient/customer. In addition, the pharmacies, wholesalers and manufacturers are being pressured for lower prices as one moves along the supply chain. At the end of October, it was reported that wholesaler [McKesson's](#) stock price plummeted (25%) because "... slowing price increases for pharmaceuticals are cutting into its bottom line."

From the news media, Congress and other pundits, all you hear about is the exorbitant prices that pharma is charging, which is in reality a practice of only a few notorious outliers. In fact, drug price increases are slowing.

The prevalence of modest price increases was not mentioned in the widespread media coverage, where middlemen like McKesson and its rivals Cardinal Health and Amerisource Bergen, are taking tremendous hits from nervous investors. The public simply doesn't understand how the supply chain works and distributors such as McKesson are already working at a low-margin enterprise business model.

McKesson CEO John [Hammergren](#) reported in an earnings conference call that McKesson year-to-date is experiencing "fewer products with price increases and those price increases are at lower rates than both prior-year results and our expectations for the current fiscal year." Hammergren also expects "full-branded pharmaceutical pricing trends to be meaningfully below those expected in Fiscal 2016." Since McKesson is not meeting either its own forecast or Wall Street expectations, its stock plummeted.

If you would like help with your pricing strategy, please contact me [here](#) or call me at 781-935-1462 to discuss it further.

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Closing Thoughts

Our healthcare system is very complex and every player involved has a symbiotic relationship to everyone else, much like systems biology. When you inhibit one player or pathway, all the other players and systems are impacted, both on-target and off-target. As demonstrated here, when there is pricing pressure on the pharma industry, the wholesale industry is adversely affected, as shown in the case with

McKesson, and the pharmacies are affected because they are getting reimbursed at lower prices, but are expected to give more services to compete on value - added when they win a contract with the insurance companies. This is why benefits plans dictate where (which pharmacy) you have to fill your prescriptions.



Everyone wants to live longer and have a better quality of life. In pursuing this quest, there is a price to pay in higher cost of drugs and healthcare.

The newer drugs are so much more complex and more time is required to understand the biology of disease mechanisms. Another reason drugs are so expensive is because the regulations for FDA approval are a lot more stringent for safety and efficacy and the reimbursement requirements are stricter today than they were 15 years ago, resulting in drugs that take longer to come to market and require more money to develop.

The mere fact that people are living longer is part of the reason healthcare costs are rising. To solve this problem, people are focusing on pharmaceutical pricing and Pharma is caught in the middle. On one hand, you have politicians and the general public, who don't understand the industry, pressuring pharma to lower the cost of drugs. On the other hand, Wall Street is demanding double - digit earnings growth and if the pharma company doesn't reach its goals, the stock drops, as was the case with McKesson and other pharma/biotech companies.

We continue to see consolidation of this industry, selling, spinning off and swapping business units as pharma companies struggle to satisfy both parties. The result of all this has been major layoffs in the industry. I mentioned symbiotic relationship, this is what happens when one area (pricing pressures and growth) is affected, other areas (layoffs) also get affected.

If there is too much pricing pressure on the pharma companies (includes biotech, medical device and diagnostic), they will not innovate. The goal of living longer or achieving a better quality of life is unsustainable in a life sciences industry filled with shrinking R&D budgets.

So how do we solve the problem of rising healthcare costs? This is not an easy fix and it requires everyone's cooperation and addressing it at multiple points, rather than pointing a finger at one specific area. I think we need to focus on what is fixable, such as medical errors (includes pharmaceutical drug errors), a problem that already has been identified. The Institute of Medicine ([IOM](#)) came out with a report in 2006, stating that if we fix medical errors, this would save the healthcare system "over \$3 billion dollars annually...(in) treating the consequences of medication errors, which does not even include lost wages and worker productivity." This could be another newsletter topic.

It appears that a lot of issues can be solved with "standardization of processes" for medical errors, drug and device fraud (already being put in place) for the safety of patients and reduce costs. All of these things will

take time and require funds upfront for a long-term gain. If we all come together, understand the system fully from all aspects of the system and put our thinking caps on, we can solve this issue. Right now, people are focusing on only one aspect of the problem, instead of the whole system.

Even though our healthcare system is broken I still believe our system is still the best, as compared to a universal healthcare system. We still have choices when selecting our PCPs, the specialists we want to see, the hospital where we want to be admitted, access to elective surgery rather than being put on a wait list, and the drugs we can take even though we sometimes must have to fight to get it.

If you would like help with your pricing strategy, please contact me [here](#) or call me at 781-935-1462 to discuss it further.

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