August 15, 2018

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month, I covered "Highlights from the BIO Convention - 25th Anniversary" If you missed last month's article, click here to read it. This month we'll cover "The Pharmaceutical Pricing Supply Chain: Will Trump's Proposal for Government Negotiation Work?"

Read on to learn more about this topic and other current news. The next newsletter will be published on September 15th, 2018.

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

Sincerely,
Regina Au
Principal, New Product Planning/
Strategic Commercial Consultant
BioMarketing Insight

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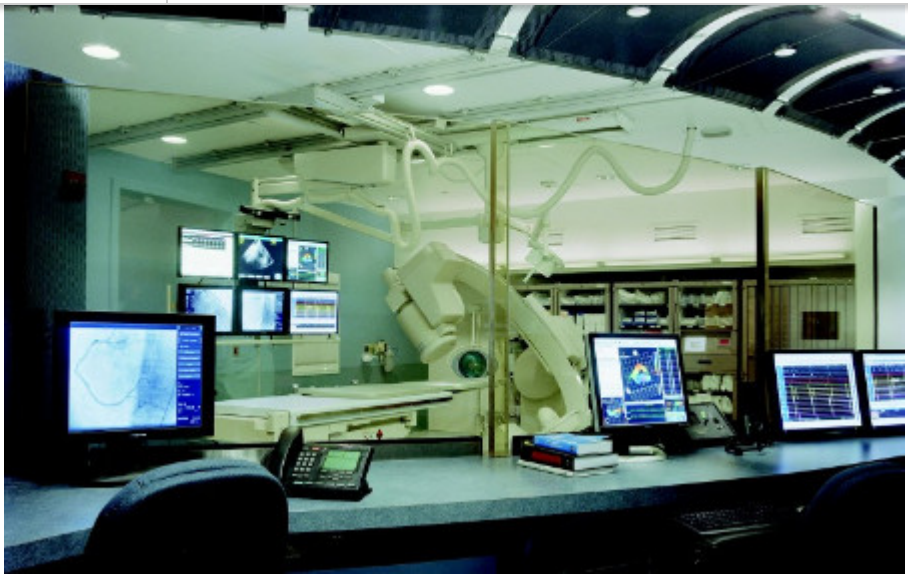

Developing a Product? Commercializing a Product?

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:

Product Development
Market Development
Marketing Strategies

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Save the Date: BioProcess International Conference - September 4 - 7, 2018, Hynes Convention Center

Development" under the Speed from Gene to Market Track on Friday, September 7th, 2018 at 8:25 am. For more information on this conference click here.

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Interview with Radio Entrepreneurs

I was privilege to be interviewed by Jeffery Davis, founder and co-host of Radio Entrepreneur, a radio station that shares the success of entrepreneurs. Click on this video to see a short clip of my interview.

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Why Our Microbiome is Important to Our Physiology and Diseases

I am pleased to announce that my article entitled "Why Our Microbiome is Important to Our Physiology and Diseases" was published in the International Journal of Clinical Pharmacology & Pharmacotherapy. This article reviews the results of the Human Microbiome Project and the factors that affect our microbiome in relation to our healthy state and dysbiosis or disease state. To read the article, click here.

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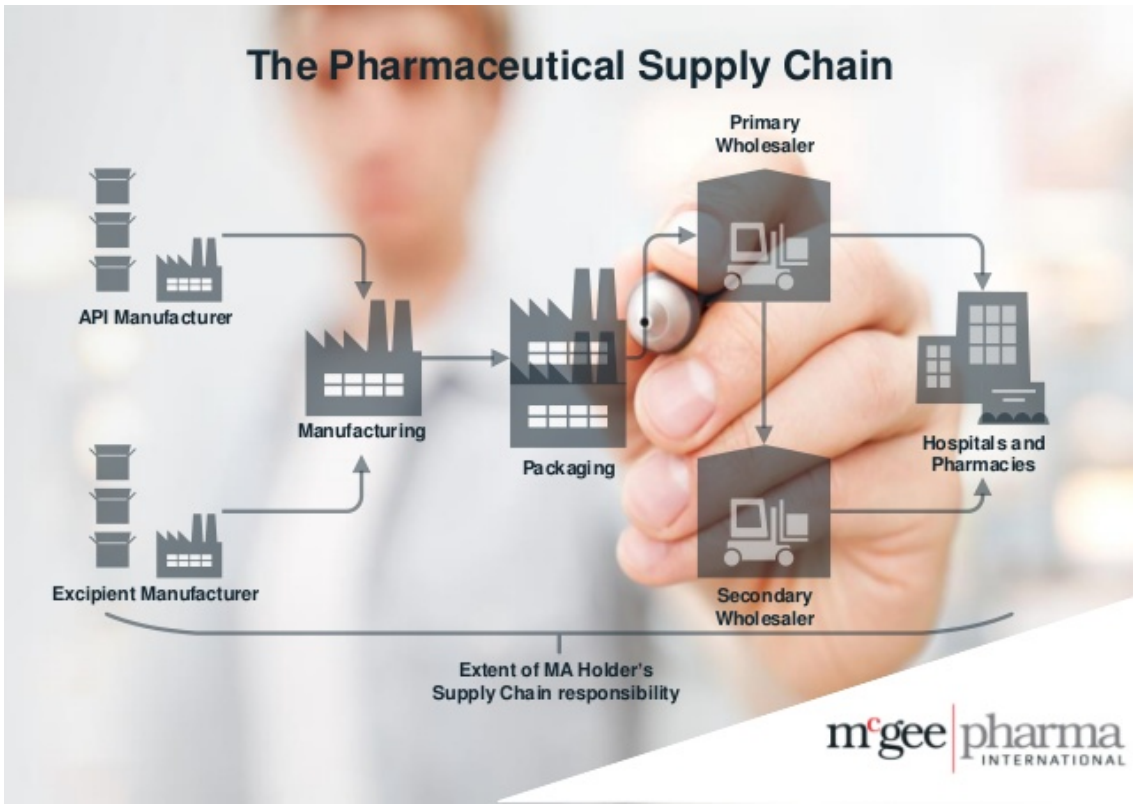
Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell Design Be Made to Cure All Types of Cancers and Will It Be Covered?

I am pleased to announce that my article on "Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell (CAR-T) Design Be Made to Cure All Types of Cancers and Will It Be Covered?" has been published in Journal of Pharmaceutics. This article reviews the mechanism, design and administration of CAR-T cells, and whether payers will pay for this new technology. To read the article, click here.



The Pharmaceutical Pricing Supply Chain: Will Trump's Proposal for Government Negotiation Work?

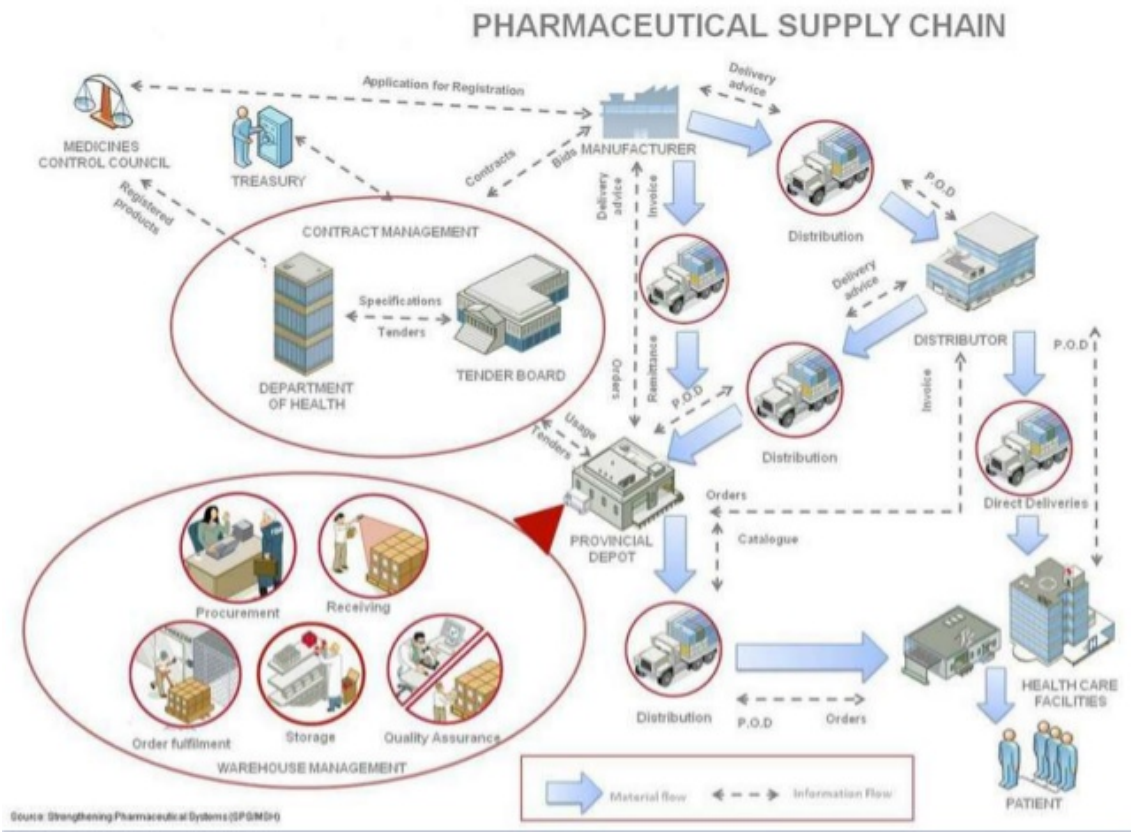
Pharmaceutical Pricing has been highlighted in the news lately depicting how drugs are unaffordable and President Trump vow to force drug companies to negotiate directly with the government on drug prices for Medicare and Medicaid. Only a few people outside of the industry truly understands how pricing works. President Trump and his administration don't understand the pharmaceutical pricing model and therefore, I question whether their proposal for government negotiation and other proposals will work. Here are four (4) reasons why:

1) The Pricing Model for pharmaceutical drugs is similar to the retail pricing template with respect to pharma companies setting a base cost (the beginning of the pricing supply chain) for their drug and a suggested retail price in the pharmacy. The model is also similar to retail in that there is a middlemen to get the product from the manufacturer to the store.

However, in order to get the drug from the drug manufacturer to the patient, there are many middlemen that are involved in getting the drug to the retail pharmacy or hospital. The following middlemen are involved: 1) Pharmacy Benefit Manager (PBMs) who negotiate price for the insurance company; 2) insurance companies; 3) distributors,

the drug for their services and pharma has no control over how much each group will add to the price in this supply chain which is the reason why pricing may vary from pharmacy to pharmacy.

This process is very complex requiring numerous steps and every drug by law needs to be tracked and accounted for from one destination to the next until it reaches the pharmacies. Insurance is also required in case the integrity of the drugs gets compromised or stolen. Each major player has its own warehouse management system. See diagram below.



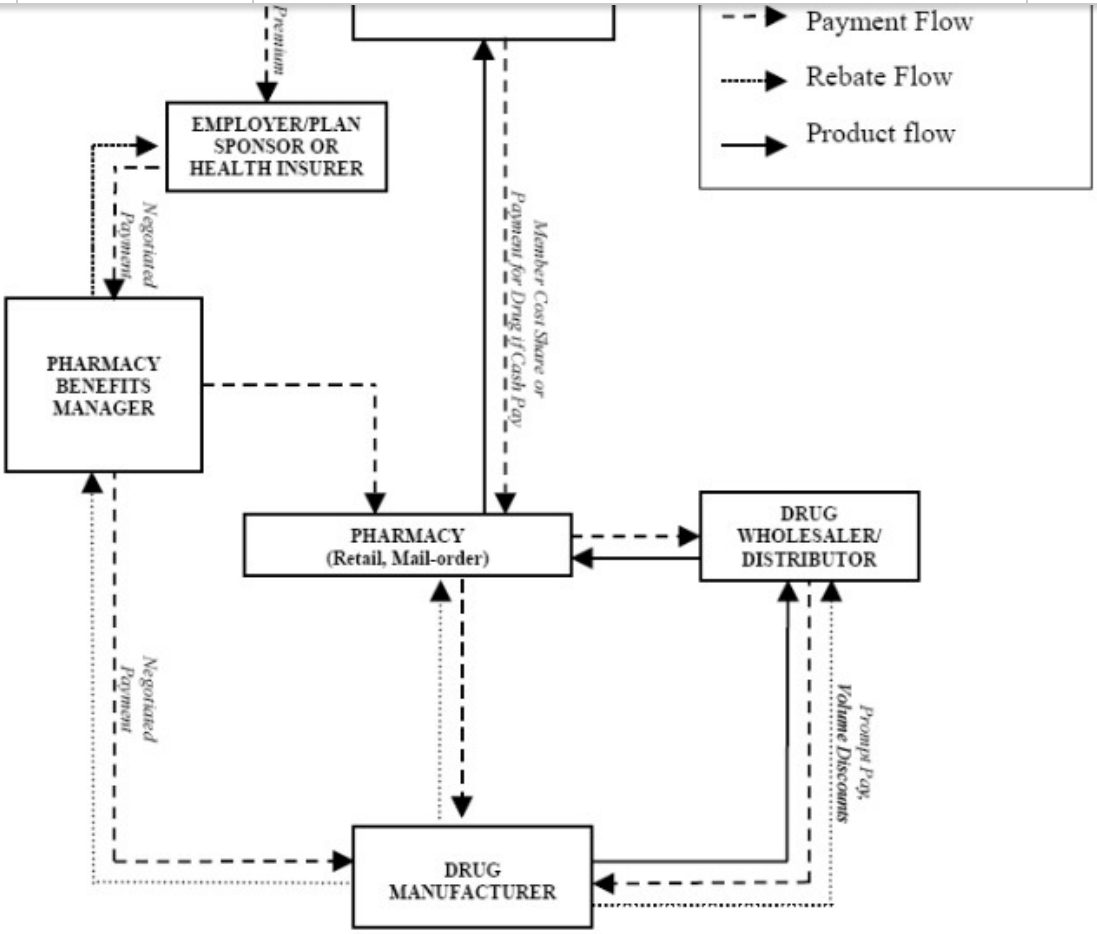
How much do these groups contribute to the retail price of the drug? When Mylan was under the microscope for their EpiPen, CEO Heather Bresch revealed that Mylan made up 45% of the retail cost and the rest of the supply chain groups made up 55% of the retail cost. Contrary to what most people believe including President Trump, it's not the pharma companies that are price gauging, because in this case it's only 45% of the retail price. Fifty five percent is the rest of the supply chain and they all have to charge for their services like any other business. See table below.

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

The one group people may not be familiar with is the Pharmacy Benefits Manager (PBM). In 2004, it was reported that PBMs (i.e. Express Scripts, Caremark, Medco) manage the prescription drug benefits for 57 percent of the U.S. population and probably well over 70 percent 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, the amounts that the pharmacy will receive and how much the consumer must pay out-of-pocket when the prescription is filled. They will negotiate with the manufacturer (in the form of rebates) and the pharmacies under regulated guidelines. They charge a fee for their services and this is one of the most significant fees out of the supply chain.

The Supply Chain Product, Payment and Rebate Flow:

When the prescription benefit system was originally set up, most patients/consumers had insurance and the patients only paid their co-pay and not the retail price. The insurance companies coverd the price of the drug (Wholesale Acquisition Cost- WAC) plus the fees of the players in the supply chain) but is rebated back through employer/employee premiums, and indirectly through patient's deductable, co-pays, and discounts from the manufacturer which is negotiated by the insurance company or the PBMs. The diagram below is a simplified version that depicts the flow of payment and rebates. This is a very complex model.



Today, insurance companies are refusing to cover the cost of medications and are passing that cost on to the employer through higher premiums (part of the higher premiums is passed on to the employee), higher deductibles and higher co-pays which is 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 an outcry from the public because there is more and more out-of-pocket expenses for the patient/customer. In addition, the pharmacies, wholesalers and manufacturer are being pressured for lower prices as one moves along the supply chain. At the end of October (2016), it was reported that wholesaler McKesson stock price plummeted (25%) because "... slowing price increases for pharmaceuticals are cutting into its bottom line."

The news media, Congress and other political leaders are constantly bickering about the exorbitant prices that pharma is charging by a few outliers, when in fact there is a slowing drug price increase that didn't have widespread media coverage. Middlemen like McKesson and 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.

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 was not meeting up to their forecast and Wall Street expectations, they stocked plummeted.

2) For many decades, all VA Hospitals were given the lowest price for all drugs that the manufacturer negotiated with anyone. Today, the VA is the biggest player with more bargaining power than Medicare. In 2011, VA health economist Austin Frakt calculated that the VA pays 40% less for drugs than Medicare. However, the VA only covers about 59% of the 200 most popular drugs, while Medicare insurers covered an average of 85% and some firms as much as 93%.

Medicare although they don't negotiate directly, already get prices negotiated through the commercial insurance firms that provide Part D prescription coverage for Medicare's 57 million enrollees. By some estimates, they may get reductions as large as possible.

In fact, it was the drug industry's support that was crucial in getting Medicare Part D (drugs coverage) enacted in 2003 — and that the ban on direct negotiation was the price of its support plus getting the Affordable Care Act passed in 2010.

How the repeal of the ban to let Medicare and Medicaid negotiate pricing would impact drug pricing, no one knows for sure. If Medicare did their own negotiations as Trump proposed, they would have to hire a whole department to conduct price negotiations. This would add cost to the government, not decrease cost.

3) Since PBMs play a critical role in negotiating rebates with drug manufacturers, they are now under scrutiny as well with some to suggest they are partly to blame for increasing drug prices partly because there is no transparency between PBMs and drug manufacturers.

In May of this year (2018), the White House plan suggested possibly looking at whether benefit managers should be considered fiduciaries, which would force them to put their customers' financial interests ahead of their own in an attempt to lower drug prices. This is ironic since Trump rejected a similar rule that put a constraint on investment advisers in the wake of the financial crisis.

However, there has been push back from PBMs. Tyrone D. Squires, managing director of Las Vegas-based Transparent Rx, a benefit manager who operates on a fiduciary model says "It eliminates the loophole of the PBM being able to leverage its clients' purchasing power."

Benefit managers don't believe a fiduciary designation will lower drug costs, said

"It's an idea whose time should never come," she said. "PBMs aren't fiduciaries for their customers and they don't want to be."

4) In the original Medicare plan, it covered Part A (hospital) and Part B (medical or physician) and one could purchase (drug coverage) through a Medicare approved private insurance company Part D. In the new Medicare Advantage plans, most plans include prescription drug coverage under Part C.

In August, Health and Human Services Secretary Alex Azar said in an interview with Bloomberg that the Trump administration are making changes where certain drugs such as infusions for rheumatoid arthritis, eye injections to treat certain conditions that cause vision loss as well as some cancer therapies that are given in the physician office or hospital and covered by Medicare, commercial insurers for Medicare will be given negotiating power for these drugs.

Currently, such drugs are paid for at their cost, plus a percentage fee for doctors, under what's known as Medicare Part B. In the commercial market, health insurers negotiate discounts of 15 percent to 20 percent or more on the same drugs for which Part B has paid full price.

Half of the savings will be required to go back to patients. In future years, the savings will be used to reduce premiums since 2019 rates are already set and patients may receive a gift card instead. I like the idea of returned the savings back to the patients, but it should be more than half. Some insurance companies have proposed that they will give the savings back to the members/patients but not everyone will receive this savings. Only those members that have a high deductible will get money back.

Azar believes health insurers will have the ability to make patients try cheaper products first, a technique called step therapy, before turning to more expensive drugs. This can create leverage for insurers to push for rebates and discounts in exchange for not pushing patients into step therapy, which can steer them to cheaper, rival treatments.

What Mr. Azar doesn't understand, is that insurance companies are already enforcing this step therapy as negotiation power. That is why insurance companies have formularies and advocate for the generic instead of the name brand. In fact there is mandatory substitution for the generic in Massachusetts and in other states. Insurance are making it very difficult to get name brand or new drugs. If patient is approved for the name brand or new drug, the patient has to pay the highest copay of that plan which can run as high as $150/month depending on the plan. This is now unaffordable for most member, so the members are forced to take the generic or less expensive alternative drug.

Closing Thoughts

The Pharmaceutical Pricing Supply Chain is very complex and contrary to what people believe, pharma companies are not price gauging because developing a drug is expensive and it is expensive to transport the drug to the retail pharmacy or hospital. The middlemen fee accounts for about 55% of the retail cost and distributors such as McKesson are already working at a low-margin enterprise business model.

PBMs have been targeted because they are the most significant fee in the supply chain and some believe they can be eliminated because the work they perform should really be part of the insurance company and PBMs are already pushing back.

Insurance companies claim that healthcare cost is out of control and that they have to charge higher premiums, co-pays etc. They claimed they were pressured to offer low cost premiums under the Obamacare exchange but the insurance companies only agreed to offer affordable healthcare insurance after the Obama administration agreed to subsidizing the insurance companies for two years. The services that are covered are sparse and member have to pay more out of pocket with higher deductible before insurance kicks in. Now that the government subsidy is gone and some States refusing to subsidized these premiums, the premiums under the exchange program for Obamacare have increased up 50%. This makes these insurance plans unaffordable again.

Everyone talks about transparency with the pharma companies, I would like to see transparency with the insurance companies since they claim healthcare cost is rising and yet they are offering less medical and drug coverage to their members while premiums are still rising. I've had my experience with insurance companies rapid rise in premiums where their pricing model did not make any sense nor were they willing to disclose their information.

think this is a good idea. When I first started with Merck, the company was a one-price house. Everyone got the same price whether you were a big pharmacy chain or a mom and pop store. Once pharmacies started negotiating price due to bargaining power, there has been tremendous consolidations where smaller stores went out of business and even today, large pharmacies chains are consolidating such as Rite Aid being acquired by Walgreens. Where is the competition? It is competition that lowers price, not negotiation power.

This problem is too enormous to just implement small quick fixes which is what the Trump administration is trying to do. Unless one thoroughly understands the system and all the players involved (including malpractice insurance) and how they connect with each other, we will never be able to lower healthcare cost. Even Accountable Care Organizations haven't demonstrated the cost saving in delivering better healthcare because to overhaul any healthcare system, it takes times and once one starts fixing one part, they will find more parts to fix which is a never ending process.

People also have to think outside the box. When Obamacare was implemented and people were wondering who was going to cover the cost of Obamacare, the Institute Of Medicine (IOM) did a study that demonstrated that preventing medical errors alone could save the healthcare system enough money to pay for Obamacare. But no one in the government took on that challenge because it is more long-term savings and a lot of work to implement.

One needs to get all the players in one room with the goal of delivering better care as a fiduciary member suggested by the White House Plans. Easier said than done and leave politics out of it.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition and economic value of your product, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.
