COMMENTARY

April 26, 2019

Dear clients and colleagues,

As health care costs in the US continue to rise at a rapid pace, the Senate Finance Committee has been holding investigational hearings on the drug industry. High prescription drug costs have become a rare bipartisan issue. President Donald Trump has made lowering drug prices one of the key issues of his administration, while the Democrats are jockeying to prove they can lead reform. Consumers, lawmakers and industry players all seem to agree that prescription drug prices are too high. What they can't always agree on is who to blame: drug makers, insurance companies or pharmacy benefit managers (PBMs).

PBMs represent a $283 billion market. Their main role is to manage the prescriptions and drug purchases of insurance companies. PBMs oversee the drug purchases of hundreds of millions of patients. The two largest PBMs, CVS Health and UnitedHealth, rank seventh and fifth in terms of profit margins among Fortune 500 companies. At the hearings, PBMs are insisting that their profits are outstripped by the cost benefits they provide in terms of buying power and generic substitution. This argument becomes less valid when you consider that three PBM companies control 70% of the industry. After all, if 70% of the industry pays the same discounted price, doesn't the discounted price become the industry price? Changing this agency style of business could save tens of billions of dollars.

The health insurance industry collects $1.1 trillion in premiums and generates $30 billion in operating profits per year. With medical cost ratios of 85% (ratio of cost of goods), the fee for managing private insurance plans totals $135 billion or a Selling, General and Administrative Expenses (SG&A) of 12.2%. If you add in Medicare plans at $700 billion, Medicaid plans at $600 billion and other programs (federal, state, third party), the total US health care market comes in at $3.6 trillion. If 12.2% (or $440 billion) of this is paid as management fees to health care plan providers, think of how much could be saved by transferring more insurance risk to the government.

Last week, Bernie Sanders proposed an aggressive bill that hands the keys of the health care system to Medicare, essentially eradicating private insurance plans and PBMs. It seems unlikely that the bill will pass due to the sheer size of the proposed change; however, it is a sign that the drama is only beginning.

The US drug and medical device industries represent a $700 billion market, and high drug and device costs are at the centre of the current debate. Take for example the price of insulin. Insulin is an old drug whose composition hasn't changed much over the years, but between 2012 and 2016 it doubled in price. The price of the insulin drug Lantus rose 49% in 2014 alone. The struggle to afford other treatments, such as EpiPens and hepatitis C medications, has been well publicized.

Why are drugs and devices more expensive in the US? One reason is that US Federal law expressly prohibits the largest insurance program (Medicare) from negotiating drug prices or making decisions about which drugs it covers. Proposed changes to legislation are underway with the introduction of the Medicare Negotiation and Competitive Licensing Act, which could give Medicare (whose membership is larger than the Canadian population) the power to negotiate prices. The savings are estimated at $14 billion for Medicare-direct negotiations.

The use of generic drugs helps curb drug costs. When a drug patent expires, generic versions can be created, and sales of the branded drug can plummet 80% overnight. According to the Congressional Budget Office, the estimated amount saved through the use of generic drugs is $10 billion.

Drug and device companies regularly implement price increases. Once a drug is deemed useful, if the price increases by 5% or less at a time, it's difficult for an insurance provider to deny treatment because of such a small increase. Some drugs, such as biologics, are manufactured using complex production technology and are difficult or very costly to replicate. Because of this, very few generic versions are created, and price increases for these drugs can be even higher.

For the past five years, the pricing practices of specialty pharmaceuticals and generic drug companies have been under scrutiny and pricing is now better controlled. Companies are learning how to do business under this new regime and valuations for this out-of-favour sector are reasonable.

This week we profile ANI Pharmaceuticals (US:ANIP)

ANI is a US-based pharmaceutical company that operates in the branded, generic and controlled substance space. The company is based in Baudette, Minnesota and operates from a 126,000 sq. ft. facility. Its products are sold in four major retail pharmacy chains (CVS, Rite Aid, Walgreens and Wal-Mart) and are included in the source programs of four major national wholesalers (AmerisourceBergen, Cardinal Health, McKesson and Morris & Dickson). Mail-order houses, including Anda, CVS Caremark and Express Scripts, as well as group purchasing organizations also carry ANI products.

The company sells 25 generic drugs and has 74 more in the pipeline. The total addressable market (TAM) for the drugs in development is $2.5 billion. ANI also sells seven branded products and has three more in the pipeline (Cortrophin gel, Crotrophin-Zinc and oral Vancoccin). The TAM for these is $1.3 billion.

ANI is planning to launch its Cortrophin gel in 2020. This is a generic version of Mallinckrodt Pharmaceuticals' H.P. Acthar Gel, which is a $1.5 billion product used to treat arthritic conditions. ANI would be the second company to market this highly complex biological drug. We expect a 50% drop in price when the generic version comes to market.

This week's commentary paints a difficult picture for the health care sector in general. However, many of the problematic industries we discussed, such as the PBM and Insurance industries, are populated with large cap companies and consequently not in our investment universe. As changes to these industries occur, we remain optimistic that disrupters to established markets, such as ANI pharmaceuticals, will emerge and outperform.

Have a good weekend.

The Global Alpha Team