

## **Paper PH-80**

### **Impact of the Affordable Care Act on Pharmaceutical and Biotech industry.**

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#### **ABSTRACT**

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (PPACA), commonly called the Affordable Care Act (ACA). The law has made historic changes to the health care system in terms of coverage, cost, and quality of care. This paper will discuss the impact the law will have on the pharmaceutical and biotech industry.

The ACA imposes several costs on pharmaceutical, biotech, and related business. A fee is imposed on each covered entity that manufactures or imports branded prescription drugs with sales of over \$5 million to government programs. In addition to the fees on branded prescription drug sales, the ACA imposes a 2.3% excise tax on sale of medical devices. The tax is levied on the manufacturer or importer before a medical device is sent to the wholesaler or hospital. Prior to the ACA, prescription drug manufacturer had to pay a rebate under Medicaid coverage which was greater of 15.1% of average manufacturer price ("AMP") or the difference between AMP and best price of the drug. The ACA increases the rebate percentage to 23.1%. It also modifies the definition of AMP, calculation of additional rebate for price increase of line of extension drugs, and expands rebate program to additional drug sales. Under the ACA, manufacturers that wish to sell their drugs covered under Medicare Part D must participate in coverage gap discount.

Along with additional costs on the industry the ACA will bring positive changes. The ACA is anticipated to add 35 million uninsured citizens as new customers who will directly impact the industry's bottom line by \$115 billion over the next 10 years or so. Under the Qualifying Therapeutic Discovery Project program as part of the ACA, a tax credit is given to companies that treat unmet medical needs or treat chronic diseases. This will significantly boost innovation, particularly for small to mid-size enterprises and benefit the overall industry. The Biologics Price Competition and Innovation Act (BPCIA), which is part of the ACA includes guidelines for market approval of "biosimilar" products, patent provisions, data and market exclusivity, and incentives for innovation.

#### **INTRODUCTION**

The Patient Protection and Affordable Care Act (PPACA), also known as the Affordable Care Act (ACA) is a U.S. law signed by President Barack Obama on March 23, 2010. Along with Health Care and Education Reconciliation Act, it represents a significant regulatory overhaul of the U.S. healthcare system since the passage of Medicare and Medicaid in 1965. In 2011, the U.S. spent 17.7% of its GDP on health care, whereas none of the other countries tracked by the Organization for Economic Co-operation and Development reported more than 11.9%. In spite of this spending there is a debate on how well the American health-care system works and whether or not it is effective. The ACA was passed into law with the goal of increasing the quality and affordability of health insurance by lowering the uninsured rate by expanding government and private insurance coverage.

Below are some of the highlights of the ACA.

- The "individual mandate" is the provision of the law that requires all Americans to have healthcare payment coverage or pay a fine.
- No one will be legally denied access to health insurance based on any preexisting conditions.
- Put young adults up to age 26 back on to their parents' health insurance plans.

- More access to preventive screenings and tests at no cost beyond insurance premiums. These tests range from diabetes, blood pressure screenings, cholesterol, breast cancer screening, HIV and other sexually transmitted diseases.

The ACA is projected to cut the national deficit by over \$200 billion during its first 10 years, and over \$1 trillion over the next two decades. The ACA is paid for through collected taxes, fees, penalties, spending cuts, and reformations to the health care industry. Health insurance marketplaces are established to facilitate the purchase of health insurance in each state. Marketplaces provide a set of government regulated health care plans from which U.S. citizens can purchase health insurance policies.

## **PURPOSE**

The ACA will have a wider impact on the overall economy. This paper will discuss the impact of the ACA particularly on the pharmaceutical and biotech industry.

## **COST OF DOING BUSINESS FOR PHARMACEUTICAL AND BIOTECH COMPANIES UNDER THE ACA**

The following are the costs and taxes imposed by the ACA on the pharmaceutical and biotech industry.

- A fee on sales of branded prescription drugs (BPD).
- Excise tax on medical device sales.
- Reduction of coverage gap under Medicare Part D.
- Expansion of Public Health Service Act (PHSA) Section 340B.
- Additional rebates to be provided by the manufacturer under Medicaid.

### **A fee on sales of branded prescription drugs**

Under Section 9008 of the ACA, any manufacturer or importer of branded prescription drugs will pay an annual fee based on its sales of branded prescription products to federal government health care programs. The fee is imposed on manufacturer with aggregate BPD sales of over \$5 million per year. The fee for a manufacturer or importer is calculated by the ratio of its gross sales from branded prescription drugs to the total of all gross prescription drugs sales for all the manufacturers and importers. The list of manufacturers or importers includes single person entity or controlled groups. The actual fee is determined by multiplying this ratio to a predetermined applicable amount. The applicable amounts for fee years are:

Fee Year	Applicable Amount
2014	\$3 billion
2015	\$3 billion
2016	\$3 billion
2017	\$4 billion
2018	\$4.1 billion
2019 and thereafter	\$2.8 billion

**Table 1. Predetermined applicable amount on sales of branded prescription drugs**

For example, if a drug manufacturer A had BPD sales of \$100 million in 2014 and the total BPD sales

for all manufacturers and importers is \$30 billion then fee paid by manufacturer A is calculated as:

$$\frac{\$100 \text{ million}}{\$30 \text{ billion}} \times \$3 \text{ billion (Applicable amount)} = \$10 \text{ million}$$

The fee is only calculated based on sales under government programs, sale of commercial sales are exempt from the fee.

### **Excise tax on medical device sales**

The ACA imposes an excise tax of 2.3 % on sales of medical devices. The law contains following four exemptions from the definition of “taxable medical devices”: eyeglasses, contact lenses, hearing aids, and devices that are purchased by the general public at retail locations for individual use. The law is open to interpretation for the last exemption because a number of devices could be purchased by general public at a retail location. For any given manufacturer the fee from branded prescription drugs is not known until the amount of total sales for all manufacturers and importers is disclosed. However the tax on medical devices is a flat amount and gives the payer more certainty of its tax liability.

### **Reduction of coverage gap under Medicare part D**

Most Medicare prescription drug plans have a coverage gap also known as the “donut hole”. The coverage gap begins after the Medicare beneficiary has spent a certain amount for prescription drugs covered under Medicare part D. Prior to the ACA, the beneficiary was supposed to pay the entire amount as out-of-pocket spending upon reaching the coverage gap till he or she reaches the start of catastrophic coverage. The beneficiary was supposed to incur the cost difference between start of coverage gap and catastrophic coverage without any help from insurers or other individuals. A significant achievement of the ACA was the reduction of the donut hole for beneficiaries. However that extra cost was passed on to drug manufacturers and the federal government. After the ACA, a drug manufacturer will give a 50% rebate to Medicare beneficiary on prescription drugs within the coverage gap. In 2014, a beneficiary will pay only 47.5% of the cost of the branded prescription drugs once he or she reaches the coverage gap. Moreover 47.5% plus the 50 % manufacturers discount is counted towards the out-of-pocket expenses so this helps the beneficiary to quickly get out of the coverage gap. A similar rule applies for generic drug payments after reaching the coverage gap. From table below it is clear that the contribution of the Medicare beneficiary in coverage gap reduces every year and more cost is borne by the drug manufacturer and the federal government.

Year	Percentage paid by beneficiary for brand name drugs in coverage gap	Percentage paid by beneficiary for generic drugs in coverage gap
2014	47.5	72
2015	45	65
2016	45	58
2017	40	51
2018	35	44
2019	30	37
2020	25	25

**Table 2. Percentage paid by beneficiary under Medicare Part D**

The reduction and near elimination of the coverage gap will be a significant cost burden for pharmaceutical and biotech companies.

## **Expansion of Public Health Service Act (PHSA) Section 340B**

Under the 340B drug pricing program, drug manufacturers are required to provide drugs to eligible health care organizations/covered entities at significantly reduced prices. Before PPACA, eligible covered entities included, among others, certain federally qualified health centers, Ryan White/HIV Clinics, black lung clinics, family planning clinics, state-operated AIDS drug purchasing assistance programs, comprehensive hemophilia diagnostic treatment centers, Native Hawaiian Health Centers, urban Indian organizations, disproportionate share hospitals (DSH) (with a DSH adjustment percentage greater than 11.75 percent), and children's hospitals. PPACA expands the entities eligible to participate in the 340B drug pricing program, assuming other statutory requirements are met, to include the following:

- Certain children's hospitals.
- Free-standing cancer hospitals.
- Critical access hospitals.
- Rural referral centers.
- Sole community hospitals.

For the newly eligible entities under PPACA, the term "covered outpatient drug" does not include "orphan drugs." Such drugs have been developed specifically to treat a rare medical condition (one which afflicts a US population of less than 200,000 people).

## **Additional rebates to be provided by the manufacturer under Medicaid**

Pharmaceutical manufacturers are required to provide a rebate for medication purchases as a condition of having their products covered by Medicaid. Prior to the ACA, manufacturers were supposed to pay a rebate which is the greater of 15.1% of Average Manufacturer Price (AMP) per unit or difference between AMP and best price of the drug. AMP is the average price paid to drug manufacturers by the wholesalers. Best price of drug is the cheapest price of drug paid by the manufacturer to its most preferred vendor.

The following changes were made to the Medicaid rebate agreement under the ACA.

- The rebate percentage changed from 15.1% to 23.1%. For example, if AMP for drug is \$10 per unit and best price of drug is \$ 8, rebate paid by manufacturer prior to the ACA is equal to greater of (15.1% of \$10 or \$10-\$8) = \$2. However the rebate after the ACA is equal to greater of (23.1% of \$10 or \$10-\$8) = \$2.31/unit.
- A line of extension drug is defined as a new formulation of a single or multiple source drug that is an oral solid dosage form that has been approved by the FDA. Under the ACA, the new rebate calculation is modified to be the greater of existing rebate formula or the product of AMP for line of extension drug, highest additional rebate for any strength of the original brand name drug, and total number of units of each dosage form and strength of line of extension drug. This will put an end to the practice of drug manufacturers evading the additional rebate by reformulating an existing drug.

## **BENEFITS OF THE ACA FOR PHARMACEUTICAL AND BIOTECH COMPANIES**

In spite of all the cost and taxes, the ACA promises a lot of benefits to the pharmaceutical and biotech companies in the form of:

- Access to prior uninsured population.
- Qualifying Therapeutic Discovery Project.
- Closing of Medicare "coverage gap"
- Compliance requirements under 340B drug pricing program.
- Comparative Effectiveness research (CER)

## **Access to prior uninsured population**

In the United States, employment based health insurance remains the most common form of health coverage. In the time period from 1994 to 2009, increase in health insurance coverage has been recorded for only four years. The percentage of non-elderly individuals without health insurance was 18.9 percent in 2009, its highest level during the 1994-2009 timeframe. This is due to job losses resulting from slow economic recovery, fewer employees eligible for coverage because of change of status to part time employment, and employees with coverage dropping it because it is too expensive. Individuals without health insurance spend substantially less on medical expenses than their insured counterparts. For example, per capita drug spending for people under the age of 65 with insurance is \$664 compared to \$223 for population without insurance. The lower spending on drugs for uninsured population can be attributed to a couple of reasons.

- The uninsured population experiences higher out-of-pocket expenses and so they defer going to the doctor, and even if they do so avoid expensive preventive checkups, treatment, or surgery.
- The uninsured population is concentrated in low economic regions of the country with less hospitals, and poor healthcare facilities.

However having access to coverage will likely increase the amount of drug spending for the previously uninsured population. In spite of initial setbacks, as of May 2014, approximately 20 million Americans have gained health insurance coverage under the ACA, and the percentage of uninsured Americans dropped from 18% in 2013 to 13.4% in May 2014. Within a couple of years, 35 million formerly uninsured citizens are projected to have health insurance under the ACA. This new population added to the insurance pool will make positive changes to balance sheets of pharmaceutical and biotech companies. It is projected that the new pool of insured populations will add close to \$115 billion of new business over a period of 10 years.

## **Qualifying Therapeutic Discovery Project**

Under the Qualifying Therapeutic Discovery Project as part of the ACA, a tax credit will be provided to pharmaceutical and biotech companies that meet a list of criteria's mentioned below.

- Therapies that treat areas of unmet medical need or prevent, detect or treat chronic or acute diseases and conditions.
- Significantly advance the goal of curing cancer within 30 years.
- Reduce the long-term growth of health care costs in the United States.

The credit is only available to taxpayers with no more than 250 employees and covers up to 50 percent of a taxpayer's qualified investment. The tax credit will provide incentives for smaller companies which are traditionally considered to be the seedbed of innovation. Most of these small and mid-sized enterprises are purchased by big Pharma and biotech companies after their molecules show therapeutic promise at the end of Phase 1 and 2 clinical trials.

## **Closing of Medicare coverage gap**

Although the narrowing or near elimination of the Medicare coverage gap or “donut hole” implies additional cost of doing business for pharmaceutical and biotech companies, it also reduces the risk that patients will switch from branded drugs to generics or discontinue therapy altogether. Since pharmaceutical companies will give a 50% discount on prescription drugs in the coverage gap, patients will continue to use prescription drugs instead of looking for alternative sources of treatment. Moreover

the number of Medicare beneficiaries has increased by 14 percent between July 2008 and July 2012 and that number is projected to grow with an increase in aging population.

### **Compliance requirements under 340B drug pricing program**

Prior to the ACA, covered entities could re-sell the drugs to patients at a higher price although they purchased it for a significant discount under 340 B drug pricing program. However the ACA has established new compliance requirements on covered entities which will protect drug manufactures. Also expansion of 340B program has created new markets for drug manufacturers.

### **Comparative effectiveness research**

The ACA established a non - profit, tax exempt corporation, known as the “Patient - Centered Outcomes Research Institute” (PCORI) to provide comparative effectiveness information to assist patients, clinicians, doctors, and policy makers to make informed health decisions. The goal of comparative effectiveness research (CER) is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, medical practitioners, and other decision-makers and responding to their expressed needs about which interventions are most effective for which patients under specific circumstances. A CER process and decision-making algorithm will boost innovation by allowing drug manufacturers to see what product features are valued and rewarded and thereby give companies a better guidance to target medication pipeline.

## **HEALTH EXCHANGES**

An important factor for the life science industry is the availability of insurance coverage that consumers choose to purchase through health marketplaces and the specific prescription drug benefits in the available plans. The marketplaces will offer different plans with different terms and conditions and this will determine the sales that drug makers stand to realize.

The impact of exchanges on drug company revenue will depend on a number of factors that will evolve over time, such as:

- The number of plans offered at each exchange, number of exchanges in each state and across the country.
- The value of rebates or discounts that drug companies negotiate with each plan.
- The type of drug coverage that is provided under each plan.
- The number of people enrolled in a given plan, their health status, and drug utilization.

## **CONCLUSION**

The ACA will increase the cost of doing business for pharmaceutical and biotech companies. Companies will pay significant additional costs for prescription drugs sold under government programs, tax on sale of medical devices, reduction of coverage gap under Medicare part D, additional rebates under Medicaid, and expansion of the 340B drug pricing program. However the ACA will also bring additional benefits to the industry by adding the newly insured population to its pool that will contribute directly to its bottom line. Also the qualifying therapeutic discovery project and comparative effectiveness research is projected to spark research and development of new products and start a new wave of innovation. It is evident though that what the companies will pay into the system is more certain than the increase in revenue. The speculation of long terms profits is a complicated process dependent

on regulatory changes, economic outlook, government policies, interest rate, currency stability, tax laws, and such other factors.

Pharmaceutical companies need to conduct a thorough assessment to understand the new landscape to identify opportunities and threats. Companies should continue to monitor exchanges as enrollment grows and the number and design of participating health plans evolve. A big jump in the use of data mining capabilities to track and evaluate medication cost and health outcomes is expected. The ACA will hasten a trend to evaluate the economic impact of medications on the overall population. The business will most likely shift from fee-for-service to fee-for-value and drug companies will need to consider providers and payers as key customers. Pharmaceutical and biotech companies need to consider providers and payers as equally important just as they think about regulators today.

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