

# Healthcare

## Reconciliation paves the way - Indian generic drug-makers to gain the most

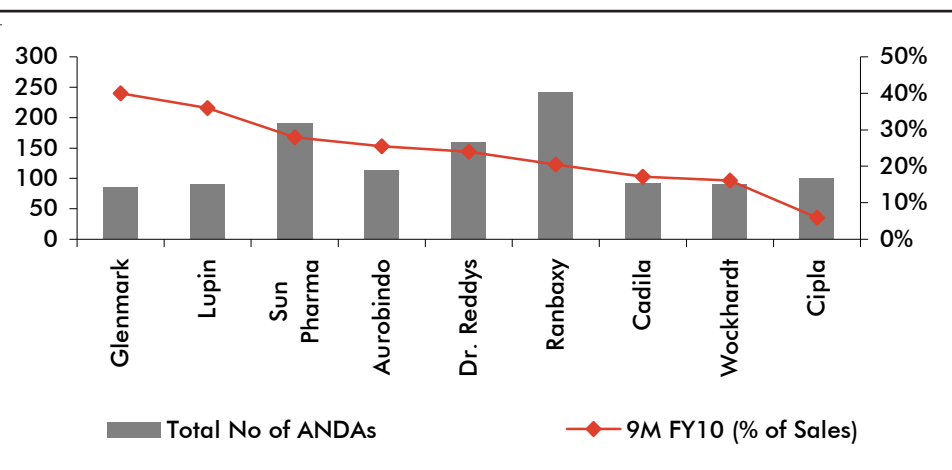
### Impact on Indian Generics

President Obama's determination for the passage of the Healthcare Reform Bill has paid off. The approval of the bill in the House is an extremely positive development for the Indian generic companies. Inclusion of 32mn uninsured Americans, Insurance market reforms and clearance of regulatory pathway for biosimilars are high impact areas for Indian generic companies and will drive future growth. Dropping the ban on pay-for-delay settlements from the bill has come as a positive surprise and should keep Indian generic companies motivated to look out for exclusivity opportunities. The bill introduces fees for drug-makers which is not a huge negative considering a low market share for Indian generic companies in the US.

The US Reforms agenda continues to be pro-generic in its overall approach and will work as a booster for Indian generic companies in the US. It is probably the right time for the US to go ahead with the reforms as drugs of over \$ 100bn value are set to lose patent exclusivities in the coming 5-6 years. Indian generic drug makers could gain as we have discussed in our previous notes as well on US Healthcare Reforms.

Among the top Indian generic companies, Glenmark, Lupin and Sun have the highest exposure in terms of percentage sales coming from the US based on 9M FY10 sales. Ranbaxy, Sun Pharma and Dr. Reddys lead the table with number of ANDAs (pending and approved).

**Exhibit 1: Indian generics - US ANDA filing and sales**



Source: Ambit Capital Research

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## **Summary of the key items of the bill which could impact Indian generic companies**

- Ban of pay-for-delay settlements between Brand and Generic drug-makers has been dropped from the agenda. Dropping the ban on 'pay-for-delay' settlements has come as a very pleasant surprise for Indian generic companies. It is believed that these settlements have resulted in a mix of 'Good' (causing early entry of generics) and 'Bad' (delaying entry of generics) settlements. This event is positive for drug-makers in general and very positive for Indian generic companies.
- Insurance coverage has been increased through various measures to include an additional 32 mn uninsured covering 95% of Americans. This has been done by imposing penalties on people and employers with no insurance, Federal subsidies to people with less than 400% Federal poverty limit (FPL) and Medicaid coverage for everyone with incomes up to 133 % of the poverty level. This is indeed positive for drug-makers, both generic and innovators as this would mean access to a larger pool of customers.
- Regulatory pathway for generic Biotech drugs has become a reality after the passage of the bill. Although product to product guidelines for biosimilars are yet to be formulated but the passage of the bill will speed up the entry of biosimilars in the US. This is positive for generic drug-makers especially the ones who have already invested in development of biosimilars. The exclusivity period remains at 12 years for branded biologics which is positive for the Big Pharma but we maintain a neutral impact for Indian generic companies.
- Insurance Market Reforms impose restrictions on insurance providers in the form of barring insurance companies from denying coverage to people because of a pre-existing medical condition and putting a cap on how much revenue can be spent beyond covering medical expenses. This should put additional pressure on the insurance providers and will translate into increase in consumption of generics as they look for cheaper prescription drugs. This is very positive for the Indian generics and negative for the Big Pharma but could pressurize margins for all drug-makers.
- Plugging the 'Donut Hole' of the Medicare Part-D program would be partly financed by Federal government and Big Pharma companies by way of subsidizing the out-of-pocket expenses of the participants. Big Pharma is a net gainer whereas the Indian generic companies are not impacted and we maintain our neutral stance.
- Creation of Comparativeness Effectiveness Centres: It supports comparative effectiveness research by establishing a non-profit organization to identify research priorities and conduct research comparing the clinical effectiveness of various medical treatments. We maintain that this is negative for the Big Pharma companies in the long run as they are already struggling with a weak research pipeline and is a neutral event for the Indian generic companies.

- Funding for reforms would also be done by imposing an annual fee on all healthcare players including drug-makers, device manufacturers and insurance providers based on their market shares. The Indian generic companies currently command a less than 2% market share of the US pharmaceutical industry and the impact would be minimal. Negative for the Big Pharma players as they command a majority share by value and neutral for Indian generic companies.

### **What happens next**

The passage of the Healthcare Reform Bill has moved in the same way as we anticipated and Democrats are following the "Reconciliation Procedure" for the passage of the bill. The House has approved the Senate bill with 219 votes in favour to 212 votes against the bill along with the changes proposed. This was the first stage of the Healthcare overhaul; the next stage would involve Senate approving some of the changes already approved by House during the next two weeks before it becomes law. Democrats hold a majority of 59 votes in the Senate and by using the "Reconciliation Procedure"; they should be able to pass the proposed changes.

# Annexures

## Annexure-1

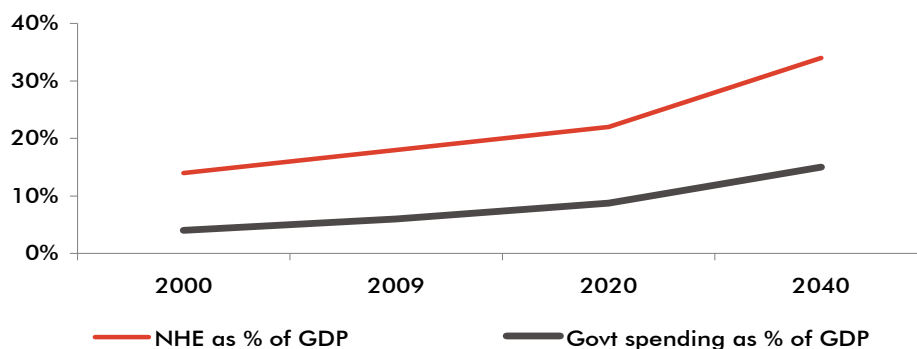
### History - US Healthcare Reforms

Pre-1970	1970-1990	1990-2010
<ul style="list-style-type: none"> <li>No major activity on healthcare reforms but sporadic reform events took place</li> <li>Roosevelt (1934), Truman (1945) and Kennedy (1962) tried for NHI (national health insurance) but did not succeed because of powerful lobbying</li> <li>In 1934, SS legislation was introduced but NHI ignored</li> <li>In 1965, Johnson introduced the Medicaid and Medicare programs</li> </ul>	<ul style="list-style-type: none"> <li>US wakes up to harsh realities of limited coverage and rising costs</li> <li>Ushered significant efforts towards healthcare reforms</li> <li>Kennedy (1971), Carter (1976) proposed a single payer system while Nixon supported a multi-payer system - none went through</li> <li>In 1988, Reagan signed the Medicare Catastrophic coverage act which was repealed in 1989 because of tax implications</li> </ul>	<ul style="list-style-type: none"> <li>Two decades of sweeping reforms</li> <li>In 1993, AHSA was introduced by Clinton</li> <li>Coverage for all, multi-payer, help for the needy included</li> <li>Could not withstand lobbying efforts of drug companies, insurance companies and medical associations</li> <li>Drug costs keep rising; Obama calls for sweeping reforms</li> </ul>

Source: Ambit Capital Research

## Annexure-2

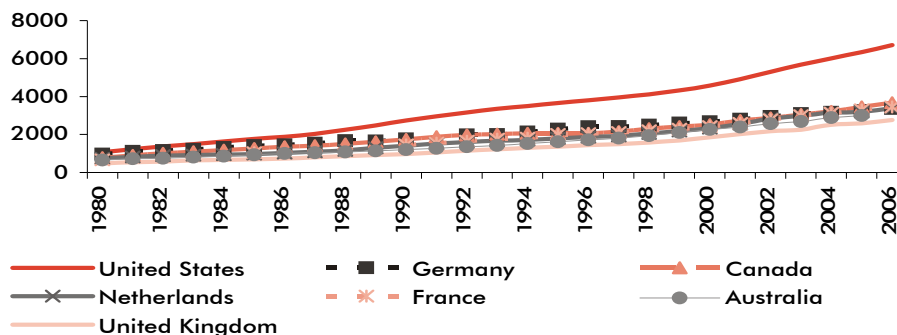
**Total National Healthcare Expenditure (NHE) and Govt spending for Healthcare as % of GDP is prohibitive and is expected to rise further**



Source: Congressional Budget Office (CBO), Ambit Research

## Annexure-3

**US has the highest per capita spend among developed countries with a lower life expectancy and lower quality of healthcare**



Source: OECD

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