HEALTH SECTOR ADVISORY COUNCIL MEETING

HEALTH CARE: CHINA AND THE UNITED STATES OF AMERICA 2011 Reforms, Risks, Rewards

PRESENTATIONS AND DISCUSSION WITH COUNCIL MEMBERS AND STAKEHOLDERS

3-4 November, 2011 The Fuqua School of Business, Durham, NC

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Challenges and Opportunities for Multinational Firms in China

Presenter: Jerome Lassa, Quality Science International

Context: Strategies for multi-national companies in China

Key learnings:

A big part of the strategy in China is to be present on the ground and build relationships with organizations such as:

The US Training and Development Agency The Central Ministry in China National and commercial providers Academia

Know the country from as cultural viewpoint

The population of china is four times that of the US. However, two thirds of the population is rural and this has implications for any type of healthcare solution. Moreover, there are huge disparities in between rural versus urban healthcare.

Healthcare status of China: Key US/China healthcare comparisons and facts

The number of hospitals in China is 20,000 compared to 6,000 in the US nearly 4 times the number in the US.

Physician/100,000 people in China: 14 Physician/100,000 people in US: 27

Percentage of healthcare expenses paid by individuals in China: 55%
Percentage of healthcare expenses paid by individuals in US: 15%

Hospital income obtained from medication in China: 42%

The number one disease condition in China are diseases related to cardiovascular disease. This is due to the high smoking rate within the Chinese population. A Think Tank in china recently reported that that the revenue the Chinese government receives from cigarette sales surpasses the forecasted expense to the government for caring for patients with cardiovascular related illnesses. This balance means that there isn't an incentive to encourage smoking cessation from the government.

Cancer rates are currently below western levels however diabetes rates are approaching international levels with 1 in 10 Chinese being diabetic (92M). With this number, China recently overtook India as the country with the most diabetics worldwide.

Figures for the incidence of AIDS in China are distorted due to inconsistent tracking. For example, a province of 89milion people recently reported 100 AIDS cases province -wide.

Obesity levels are rising particularly amongst children. This is due in part to cultural factors such as the one child policy which means that there is a tendency to overfeed children.



There are huge changes afoot in the healthcare IT space. If you want to know what the market is in China, then know what the government is spending.

On average, China's healthcare system is estimated to be 10 years behind that of the US. However due the population size, number of facilities in the country and current healthcare reforms, opportunities abound for US companies in the healthcare space. Healthcare reform aims to tackle the following:

- Increase the number and quality of healthcare facilities
- Establish universal healthcare insurance
- Reform pharmaceutical and drugs distribution
- Improve public healthcare, especially related to pandemic and infectious disease control
- Public Hospital reform aimed at better training for professionals and increased investment in healthcare IT

The State Council wants to implement plans that focus very heavily on healthcare IT as part of these reforms. The aim in the future is for the Chinese system to leapfrog many of the problems the US healthcare system faced in refining its healthcare system.

As a result, there are lots of ancillary opportunities in the healthcare IT space. However, it is important for companies to have partners in government in order to know what the funding stream for the future looks like.

Challenges and Opportunities for U.S. Suppliers

The US Trade and Development Agency (USTDA)

The USTDA helps companies create U.S. jobs through the export of U.S. goods and services for priority development projects in emerging economies. The organization has been instrumental in connecting US companies with healthcare organizations in China with the aim of moving along processes for US

companies in China but also to help the Chinese plan, conduct training and introduce capabilities to help them leapfrog many of the problems the US healthcare system faced in refining its healthcare system.

There are lots of opportunities for US technology suppliers in China

Hospital operational opportunities

- The average length of post-operation hospital stay in China is fifteen days compared to five days in the US. Hence there are opportunities for service lines to reduce post-operation patient hospital stay.
- Time from admission to operation is also much longer in China. One explanation for this is because there are no physician practioners is China. Therefore, much of the pre-op work has to be done in the hospital.
- Pain management approaches
- Clinical pathway information services
- Joint Commission Accreditation services
- Innovation incubator in a research collaboration model

Challenges for US HIT companies in China

Chinese provincial, municipal and central ministries are very autonomous and exhibit competitive behavior. Hence it can be difficult to see how funding flows to any one of these levels. It is not a natural cascade down so you need to have relationships at all levels if you want to deal with them. This also makes planning for technology quite difficult because bringing together the different stakeholders is a huge challenge.

Funding is very incremental and rewardincentive based. It is not uncommon that companies are required to demonstrate outcomes before receiving a new level of funding. This can mean that companies have to pull back because the client does not have access to the level of funding until companies have demonstrated results on a small scale first.

Lack of certification standards even in the lab sector is also a huge problem, adding to the integration problem. Additionally, there are over a thousand independent software vendors to hospitals and clinics in China. Many of these companies have their own proprietary software and programming which leads to interoperability problems.

Lack of adequately trained medical professionals and health informaticists

Large rural health population requires different HIT solutions

HIT Opportunities for U.S. Suppliers

- Funding channels: forge relationships with government health bureaus to learn of central ministry priorities and funding, help them achieve compliance
- Demonstrate opportunity for data standards to better document, quantify and improve care plus enable efficient HIT adoption
- Demonstrate leading integration solutions that bridge and leapfrog a fragmented HIT landscape (e.g., cloud computing)
- Translate proven certification frameworks to fit the China way (e.g., U.S. CCHIT)
- Offer training for medical professionals and health informaticists
- Bring demonstrated solutions in teleeducation and tele-medicine from the
- HIT market estimated at \$1.8 billion in 2010

Health System Management Challenges for U.S. Suppliers

• Limited evidence base and research capacity in care protocols (acute, ambulatory)

- "Questionable" incentives for clinical, operational and financial improvement (e.g., overutilization of resources)
- Early stages of demand (central ministry and consumer) for threshold quality
- Traditional Chinese Medicine approaches dominant and sometimes conflicting with Western Medicine
- Very early stages of rehab and long term care

Health System Management Opportunities for U.S. Suppliers

- Catalyze transfer of U.S. evidence base; build research capacity (more in Case Study 3)
- Demonstrate unfavorable impact of current incentives (lab, pharmacy overutilization)
- Accreditation (e.g., Joint Commission, ISO, etc.) to drive up threshold quality
- Catalyze integration of TCM and Western Medicine (more in Case Study 3)

• Very early stages of rehab and long term care

Pharmaceutical Research Partnerships Challenges for U.S. Suppliers

- Adherence to international research standards, scientific methods, and research efficacy
- R&D in early stages of development
- Intellectual Property Protection (IPP)
- Cuts in drug prices, drug distribution

Pharmaceutical Research Partnerships Opportunities for U.S. Suppliers\

- Helping achieve Good Clinical Practice (GCP) stature through compliance with international standards, scientific methods, and research efficacy
- Contract Research Organizations (CROs)
- Chinese Over the Counter (OTC) market
- Pharmaceutical market estimated at \$20 billion by 2012

Panel Discussion: Opportunities and Challenges in the China Market

Bryan Frist: Chinaco Healthcare Corporation

Jeffrey Spaeder: Quintiles; Jeff Henderson: Cardinal Health Sandeep Duttagupt: Pfizer

Key learnings

Participants noted the following key issues about doing business in China:

- 1. Timing is key
- 2. Fully localized team
- 3. Adaptation to local customs
- 4. Relationships: Need to have a top down bottom up approach
- Doing business in China is no more complicated or harder than it is in the US
- 6. Watch where the competition is going
- 7. The evolution of healthcare in China will be different than the US
- 8. Be prepared to adapt to change:
 However, the next three years are significant because many of the systems, processes and infrastructure that will determine the next fifty years will be set.
- 9. Be prepared to invest considerable resources (management, time and capital) into the country
- 10. Scarcity of immediate talent as well as talent retention and development are the biggest challenges to doing business in China.
- 11. The cost arbitrage for performing clinical research in China: 50% less expensive to perform clinical research in China compared to other developing countries.
- 12. Participants' experience with joint ventures shows that they can be difficult to handle. All advice joint ventures with a majority stake and also partnering with the local authorities if possible.

The myth that when the Chinese government is the predominant payer, it is difficult to make money has been debunked

Both the US and Chinese governments pay somewhere between 50-55% percent of healthcare. (although most statistics agree that the US government pays more). The major difference between the two healthcare systems is private insurance. Private insurance takes up most of the rest of the healthcare spend in the US whereas in China, this represents only 5-15%. The remainder is cash out of pocket expenses for patients.

Although some might see this as a difficult situation to do business in, this view can be countered by the fact that you are dealing with patients who will be making individual decisions based on the relative value of your products and services rather than with powerful governments agencies or private insurers with a large amount of power and they make decisions based on factors other than what most consumers make their decisions on. Such a cash based customer base is very discriminative of what they buy and will require significant value for money. Hence, in a healthcare system rife with counterfeiting, US companies with brand integrity have a unique opportunity to gain significant market share.

The concept of leapfrogging means that China's improving healthcare system will catch up to that of the US much sooner than the several decades many predict

This happened in telecoms where China essentially skipped hard-wiring and moved on to smart phones. Similarly, China's healthcare system will skip most of the growing pains the US experienced in defining its healthcare system based on the experience of the US and other

countries. Although, legacy infrastructure influences the path China takes, the country is starting from quite a low base and therefore has an opportunity to design its healthcare system with the future in mind. Furthermore, China has an advantage because there aren't as many vested interests in its healthcare IT infrastructure as there are in the US making integration and interoperability much easier.

Overview of healthcare research in China

Overall healthcare is overseen by the ministry of health. Overall clinical development is overseen by the State Food and Drug Administration (SFDA). There is relatively modest investment into basic research in China but there is an ongoing commitment to commit \$60 billion in R&D over the next five years to basic science research which represents only a tenth of what the NIH in the US spends. Additionally, there is no equivalent NIH type function in China.

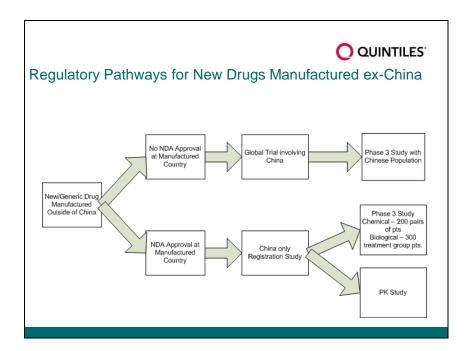
A number of multi-national pharmaceutical companies have elected to establish research facilities in China. There are a number of reasons why companies may choose to do so beyond the obvious cost arbitrage issue. Chinese corporate tax rates are very high should companies decided to extract profits from the country. Instead of paying that tax, many pharma companies have decided to invest back into China through their clinical research function. Although China doesn't have a long history of clinical research, the country is developing the talent pool as pharma companies continue to invest in talent. Eventually, there may be a shift as this talent migrates to the 35,000 small and local and mostly generic pharmaceutical manufacturers that populate China. As this shift occurs, the "duplication" business model employed by these small

pharmaceutical companies will start to give way to a culture or innovation whereby we will start to see new and innovative therapies coming out of China.

Regulatory Pathways for New Drugs Manufactured ex-China

For a drug to get into the Chinese market, studies must be carried out on the Chinese population first even if the drug is approved everywhere else in the world. Firstly, it has to undergo a pharmacokinetic bridging study to determine if the exposure of the drug in the Chinese population is the same as the exposure in the population in which it was tested elsewhere in the world. Secondly, the drug has to undergo phase III studies to show safety and tolerability and also to give physicians experience using the drug in the Chinese population. Registration studies that lead to market approval in China must also be performed in and SFDA approved sites. This creates a problematic bottleneck as there are only about 2000 of these sites across the China. Additionally, only about 200 are approved to perform cardiovascular research.

These SFDA facilities are usually large government affiliated hospitals usually associated with a well respected medical university and have a special clinical department similar to any large academic hospital in the US. Although the equipment is usually up to date, the physical planning of the hospital can be quite aged. Due to the high throughput rate of the SFDA approved sites and Chinese hospitals in general, it makes it easier to enroll clinical subjects once you have access to them even though there are relatively few of them compared to the overall Chinese population.



Challenges of performing clinical research in China

- 1. Difficulty of getting SFDA approval for your protocol to be performed in China
- 2. Uniqueness of disease presentation in China- there are patho-physiologic differences in the way some diseases present in the population.
- 3. Standard of care is different.
- 4. Different genetic characteristics
- 5. Cultural issues as concept of clinical research is new in China. Therefore patients can be wary of participating in clinical research.
- 6. Consumerism of drug use in China means that patients can be skeptical about whether they really need the drug they are being enrolled into clinical research for. Patients are often

concerned that doctors might be benefiting financially enrolling them on the drug.

Intellectual Property (IP) issues

IP is still an issue in China. To a large extent, involvement in the process of defining the shape of IP in China represents part of the business model for may US companies seeking to conduct long term business in China. For pharma and healthcare companies, this involves significant hand holding and guidance with the future in mind that when local Chinese companies themselves start innovating in healthcare, then the issue will also become even more pertinent.

For service companies, IP occurs in the shape of their trained staff and the issue of retaining them at the company.

Anticipating and planning for payment modifications

Panelists:

Scott Walton: LabCorp David Cannady: HCA

Deleys Brandman: Insigma US

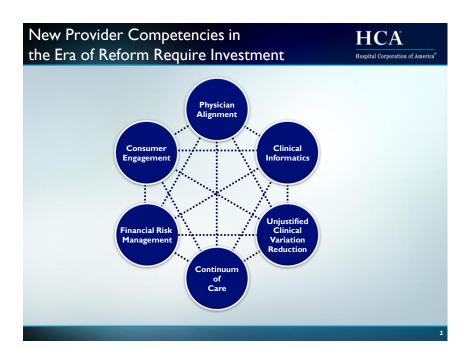
Maureen O'Connor: Chief Strategy Officer, Blue Cross and Blue Shield of North Carolina

Provider perspective:

Panelists noted that the current state of healthcare reform in the US means that we are currently faced with an era of uncertainty as companies anticipate and plan for payment modification. Key views from hospital providers include:

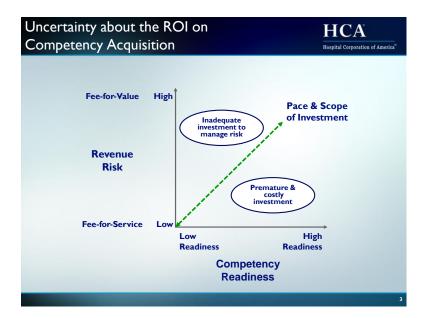
 Most are favorably inclined toward healthcare reform efforts even though they recognized that they would experience cuts in reimbursement. This cut is offset by the uninsured patient population issue finally being addressed by the universal coverage aspect of the healthcare reform bill.

It was noted that as the US healthcare system transitions from a fee-for-service to a value-for-service system, providers will have to examine some of the competencies required to prepare their organizations for this new era. This is partly because hospitals will have to become providers of care across the entire healthcare continuum. Competencies identified include:



Acquiring these competencies will require significant investment, but the current uncertainty in the healthcare space means that investing to develop these competencies at the wrong time could also be a costly mistake both

from the cost perspective and a utilization and outcomes perspective.



Payer perspective

Panelists focused on the following issues:

- 1. The current healthcare environment means that organizations cannot keep tracking on as before
- 2. Initiatives to drive payment reform
- 3. Impact of payment reform on the market circa 2014

Some of the changing dynamics observed by panelists over the past two years include:

- Consumer buy-down (ie: the level of benefits that people buy continues to erode with the effect that there is more out of pocket expenditure for the consumer). This shift in cost to the consumer, as long as is affordable is not necessarily a bad thing.
- A decline in the individual and small group insurance book of business. This is partly due to the stagnant economy but also because the growth in medical insurance currently outpaces CPI growth by a significant margin. Hence many small employers cannot afford coverage

- anymore and many individuals are opting out of medical insurance because they cannot afford it anymore.
- For bigger companies especially those in retail with a high proportion of part time staff, "employer dumping" is also being actively considered whereby these employers are opting to pay for their employees to obtain their medical insurance on the exchanges when they finally come into effect.
- Not all the stakeholders in the healthcare continuum will be aligned at the same time, hence there will be a period of schizophrenia associated with healthcare reform.
- The way payers interact with hospital systems is also changing. There is a shift in the way payers and providers define and negotiate success parameters. There are now genuine conversations about how the system has to be changed focusing on better healthcare service design and delivery with a view to achieving better shared patient outcomes.

Clinical lab's perspective

Some Background on Pricing/Payment in the Lab Business 3-4% of the spend impacting 75-80% of medical decisions - 50-55% of market is in hospitals - Hospitals prices are 5-10X higher than national reference labs - The holy grail for diagnostics = value pricing - Many "operational"/informatics/structural barriers to value pricing

Due to the minimal impact clinical lab expense has on overall healthcare cost, providers and payers are not incentivized to change their behavior in the value-based-era of health care.

As the US healthcare payment model continues to switch from a fee base model to a value based model, testing per unit and pricing per unit will decrease. To be the partner of choice, LabCorp is embarking on the following:

What is LabCorp Doing to be Ready?

- Continuing to drive efficiencies and expand reach
- Improving our flexible IT platform/ "open source" model to connect with others
- Implementing a two-pronged decision support strategy
- Protecting the diagnostics innovation model
- Going to China

LabCorp

Additional insights:

- Although many hospitals in China are trying to move toward EMR for patients, it is still illegal to function electronically as a hospital in China. Hence in addition to collecting electronic patient information, hospitals must also collect patient information on patient charts.
- There is very little collaboration between hospitals partly because it is

- tedious to move paper information around.
- Due to the high level of out of pocket expenses borne by patients in China, the government is investing in measures to determine the efficacy of expensive drugs on the Chinese population.

Implications of US payment reform for health care segments

Speaker: Dan Mendelson, Avalere Health

Key points

Important environmental issues in the healthcare Industry in an era of deficits, health reform and environmental change.

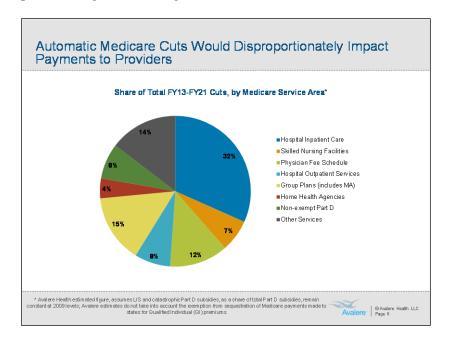
- 1. Debt Reduction and the Economy
- 2. Reform Coverage Expansions (Medicaid and the Exchanges)
- 3. Individual Mandate Scenarios and the Commercial Book
- 4. Pricing & Utilization Pressures in Acquisition of Technology
- 5. Payment and Delivery Reform

Debt Reduction and the Economy

This summer, Congress passed and the president signed the Budget Control Act of

2011 (BCA) that put in place a process for reducing the deficit. The BCA imposed caps on future discretionary spending and empowered the "Supercommittee to identify additional deficit reduction by Thanksgiving. The Supercommittee is charged with finding \$1.5 trillion of additional savings. If Congress and president fail to enact a bill to reduce the deficit by at least \$1.2 trillion, the BCA will impose automatic spending cuts (known as sequestration) to achieve \$1.2 trillion in deficit reduction.

The Sequestration is the preferred outcome for most healthcare companies because an automatic reduction in healthcare across the board, as is the case with the supercommitee's efforts would disproportionately impact payments to providers the most.



This is because, the supercommitee's cuts are according to Medicare revenues but if cuts are apportioned based on profitability, then pharmaceutical companies loose out more. As a result of this, there is significant lobbying for failure because this is in pharma's best interest.

Hospitals are also beginning to lobby for sequestration because the cuts don't start till 2013. Which means that they will have a whole election year to lobby so that the cuts actually never happen.

All this means that we will have a prolonged period of continued discussion about the deficit and how it affects healthcare. Stakeholders will be faced with continuing pressure on margins but at the same time, companies that focus on cost reduction will find new opportunities.

Reform Coverage Expansions (Medicaid and the Exchanges)

Coverage expansion if the ACA if implemented means that players will have to focus on the following three:

- The exchanges
- Employers
- Medicaid

Additional points:

- While the Essential Benefits Require Drug Coverage and an OOP Cap, Exchange Plans Will Be Less Generous than ESI
- New Eligibility Rules Will Also Increase Medicaid Enrollment by More Than 30 Percent in Over Half of States
- Many States Have Been Slow to Establish Exchanges, Making the Design of the Federal Fallback Increasingly Important

 Generic Drug Use in Medicaid MCOs is Increasing, and could be the Norm in Exchange Plans. Depending on the essential benefit requirements, exchange plans or Medicaid benchmark benefits could have generic-only formularies.

States are rapidly shifting their Medicaid Beneficiaries from Fee-for-Service into Managed Care.

Why the Increased Use of Managed Care?

- MCO enrollees eligible for mandatory drug rebates
- capitated contracts improve states' budget predictability
- MCOs better at coordinating care and reducing costs
- States preparing for Medicaid expansions and exchanges
- Optimism about care for the Duals through MCOs

The Individual Mandate and the Commercial Book of Insurance

The Supreme Court Decision on Individual Mandate is the Greatest Threat to ACA. In the short term, employer-sponsored health coverage is expected to be stable but uncertain in the longer term. In particular, if exchanges offer greater value, it is expected that larger employers and workers may seek access to them.

Pricing & Utilization Pressures

It is expected that health plans as a whole will increasingly find their margins squeezed as a result of market trends and the ACA. Therefore their negotiating position in markets where they don't have a dominant position will be increasingly weakened. The emergence of evidence based medicine and comparative effectiveness research also means that manufacturers no longer enjoy the position

they used to of having the dominant information about the new products they introduced onto the market. Many stakeholders now also have large amounts of data about the product: (eg: PCORI etc). There are range of government agencies focused on obtaining maximum value for the product.

Payment & Delivery Reform and the Role of Measurement and Evidence

The reality of Healthcare Today Necessitates Delivery Reform. Aligning Incentives is Critical for Changing Healthcare Payment and Delivery to Solve Cost and Quality Problems. Moving forward, payment reform will force hospitals to build new competencies which could alter their thinking about drugs

Strategic opportunities

Strategic Opportunities

- New starts that capitalize on the fiscal environment
 - » Cost savings (PBM for LTC)
 - » Insurance change (ClearCost)
 - » Health IT (arguably Verizon)
- Acquisitions for cash-rich health plans
 - » Health systems / provider control (Coventry/Childrens)
 - » Investment in quality and health IT methods (Ingenix)
 - » Government programs (Aetna/HealthSpring)
- New strategies for PhRMA
 - » Generics / FOBs / Companion Diagnostics / Health Enhancement
 - » Spinoffs (market does not value R&D)

