



Global Health Care and the Role of Innovation: THE PAIZABIO PERSPECTIVE

 **PAIZABIO**[®]
For China, In China, To Western Standards

ABOUT THE AUTHOR



Stuart Rose, PhD

Stuart Rose is the founder and chief executive officer of PaizaBio, LLC, a contract manufacturing organization focused on assisting western pharmaceutical companies with manufacturing sterile injectable drugs in China for the Chinese market. An established entrepreneur and investor, Dr. Rose spent four decades in the pharmaceutical industry and has extensive experience in manufacturing and logistics in international markets. He has spent nearly ten years learning about China and its business practices, forging a strategic partnership with Ausia BioTech in Hangzhou; he has deep respect for China and its people.

Dr. Rose is also the founder of two high-tech business incubators in Albuquerque, New Mexico (USA), The BioScience Center, which concentrates on early-stage biotechnology companies, and FatPipe ABQ, which is dedicated to information technology companies.

Dr. Rose is honored to be a guest of Tsinghua University and the 2015 China National Science and Technology Cooperation Week.

PaizaBio - The Portal for Western Healthcare Companies Seeking Manufacturing: For China, In China, to Western Standards



With nearly 1.4 billion citizens, China's population is larger than North America, South America and the European Union combined. Its economy has expanded exponentially. The per capita increase in gross domestic product (GDP) has increased 30 fold over the last 35 years. China's economy is second only to the United States and leads the world in attracting foreign investment.

While both the BRICs (Brazil, Russia, India, China) and MINTs (Mexico, Indonesia, Nigeria, Turkey) emerging markets are impressive, nothing in the world rivals the China Opportunity.

GDP and Projections for Emerging Markets - Rise of the BRICs and MINTs (\$ trillions)



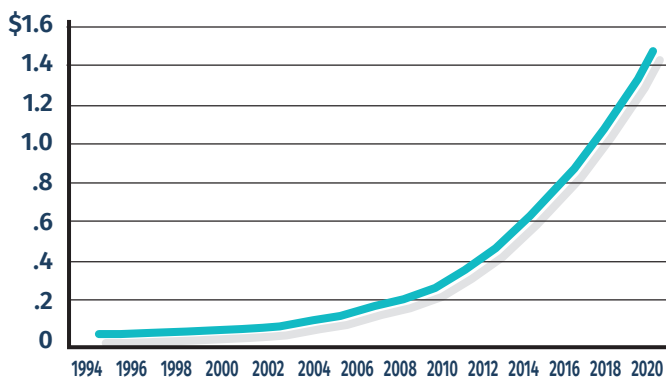
Source: World Bank, Goldman Sachs

Even though China's per capita expenditure in the healthcare arena is a fraction of that of the West, increasing affluence and attention to public health in China is on the rise. Government policies seek to level the playing field between urban and rural areas, the latter of which has historically suffered from a lack of access to modern medicine.

This convergence of increasing affluence, growing public health awareness, and political support for better access across the nation have made China one of the fastest growing healthcare markets in the world.

According to McKinsey, China's healthcare spending is projected to grow from \$357 billion in 2011 to \$1 trillion in 2020. According to IHS data, spending is projected to grow from \$323 billion in 2011 to \$1.46 trillion in 2020.

China's Total Health Spend (in millions USD)



Source: IHS Healthcare and Pharma WorldMarkets Healthcare and Forecasting 2013



Western-Based Healthcare Companies that Want to Grow Must Be in China

With 21% annual growth from 2007-2012, China is the fastest growing country in the world for pharmaceuticals.

What is even more attractive to Western companies is that, while currently experiencing a transient slowdown, China's pharmaceutical market is projected to grow at multiple digits for the foreseeable future. At the historic rate of growth, China will reach equivalency to the United States, in value, as early as 2021.

China's pharmaceutical market expansion comes at a time of stagnant, and in some cases, contracting growth in the United States and Europe. This stagnation is the result of increasingly maturing product markets, highly profitable drugs losing patent protection and the political reality of paying for the health care of an aging population, all of which threaten company profits.

China represents an unparalleled growth opportunity for Western pharmaceutical companies. While it is not uncommon for Western companies to have a manufacturing presence in China in the areas of solid and oral drugs, the aseptic injectable drug market has remained elusive and largely restricted to imported drugs. This has created an untapped market for aseptic drug production in China.



PaizaBio: Focused on the China Opportunity

In entrepreneurial business environments, people look for opportunities that can be solved through a new technology or company. In the case of PaizaBio, a businessman experienced in pharmaceutical manufacturing and logistics recognized the opportunity of manufacturing sterile injectable drugs for the Chinese market, in China, to Western quality standards. PaizaBio, LLC, was founded at the BioScience Center, a business incubator in Albuquerque, New Mexico.

PaizaBio offers contract manufacturing of aseptic fill-and-finish drugs to Western companies currently operating in or seeking to expand in China.

PaizaBio provides access to China's leading contract manufacturing organization (CMO), Ausia BioTech, which has specialized in the manufacture of sterile injectable drugs for more than two decades. Dedicated to ensuring absolute quality in aseptic processing and lyophilization, PaizaBio has incorporated industry-leading technical training and quality management systems, providing clients with complete transparency of the manufacturing process.



PaizaBio employs multilingual customer service teams composed of Chinese and American professionals who support quality, communications, and confidence among clients throughout

each project and strategic partnership. PaizaBio also provides expertise in Chinese regulatory compliance practices via cFDA, facilitating new product registration and faster time-to-market.

Recent changes in China's policies make manufacturing drugs in China for the Chinese market more attractive to Western companies. Contract manufacturing organizations in China can now serve as the principal manufacturer for a drug approved in China held by a research-based company or organization. Innovative foreign drugs manufactured in China will have access to a new fast-track approval process. For clinical development, the cFDA's drug approval process will be streamlined into a one-time overall regulatory approval instead of requiring companies to secure separate approvals at each phase, thus speeding approval of marketing authorization for new innovative drugs. These changes support PaizaBio's position as the portal of entry for Western pharmaceutical companies seeking an immediate, growing presence in China.

Health Care as a Global Priority: Opportunities for Innovation

Regardless of which macro-level economic designation, least developed, emerging or developed economy, in virtually every country in the world expanding access to health care and improving public health are priorities of national policy.

Healthcare spending represents one of the single largest segments of a nation's Gross Domestic Product (GDP) currently accounting for 10.6% of global GDP and is projected to grow more than 5% each year for the remainder of the decade.

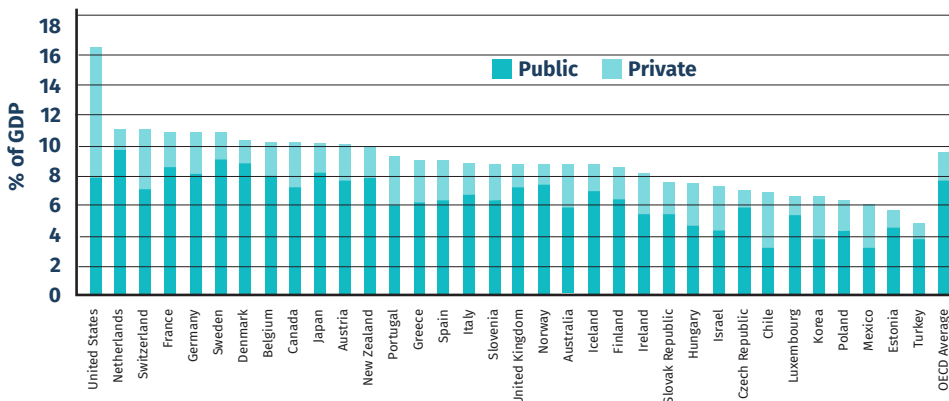
The current value of global healthcare spending is calculated at more than US\$7 trillion and is forecast to rise to nearly US\$ 10 trillion by 2020.

In developed markets, as defined by the OECD countries (Exhibit 1), spending on health care as a percentage of national GDP averages 9.8% with an approximate 3:1 ratio split between public funding sources (government) versus private funded (private insurance and out-of-pocket*). Only in the United States does healthcare spending account for a significantly larger share of the national economy and this is directly related to the much higher price charged for healthcare services and products.

U.S. health spending is one and a half times as much as any other country, and nearly twice the OECD average.

Exhibit 1

Total health expenditure as a share of GDP



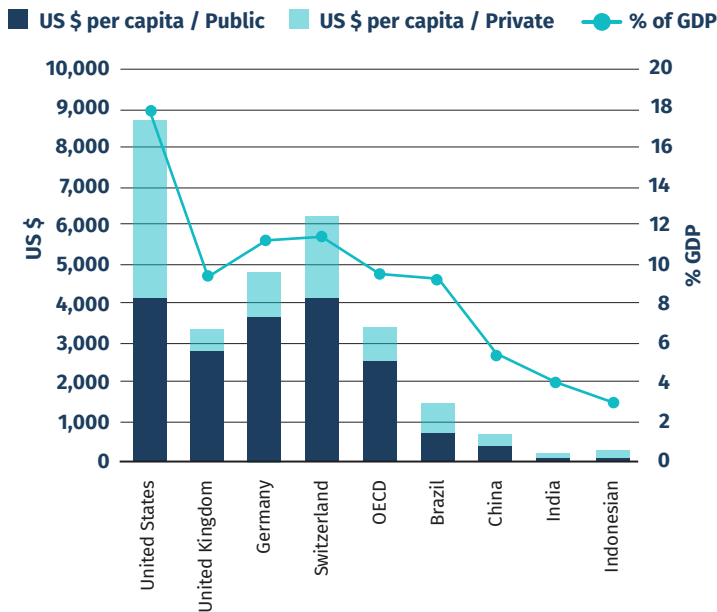
SOURCE: OECD Health Data 2012

*NOTE: Percent of Private/Patient, "out-of-pocket" expense ranges from ~33% in Brazil, China and Russia; 55% in India; and 10-12% in the United States and European Union.

In developing or emerging markets, (Exhibit 2) healthcare spending as a percent of their economy is much lower than in developed countries and, in terms of absolute spending per person, significantly lower. This difference in emerging markets spending will play a major role in the strategic business planning for most multinational healthcare companies in the foreseeable future.

Exhibit 2

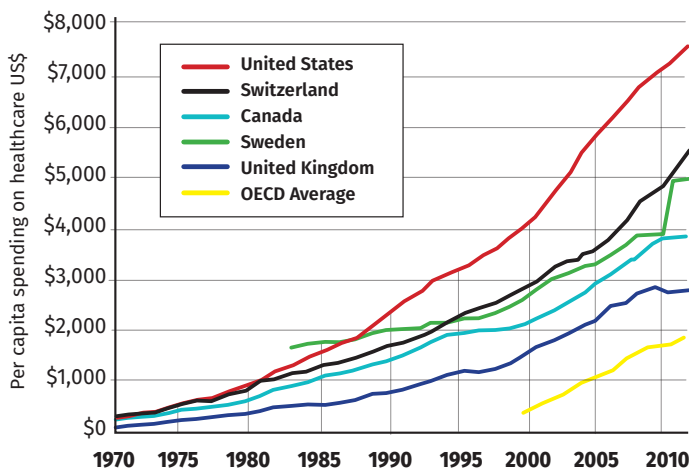
A Comparison of Key OECD National Economies vs. "Select" Emerging Markets



Source: OECD Health Data 2010 <https://data.oecd.org/healthres/health-spending.htm>

While emerging nations have just begun to prioritize and fund health care, in developed market economies health care represents an increasing significant resource commitment.

Growth in Total Health Expenditure Per Capita OECD and Selected Countries, 1970-2012



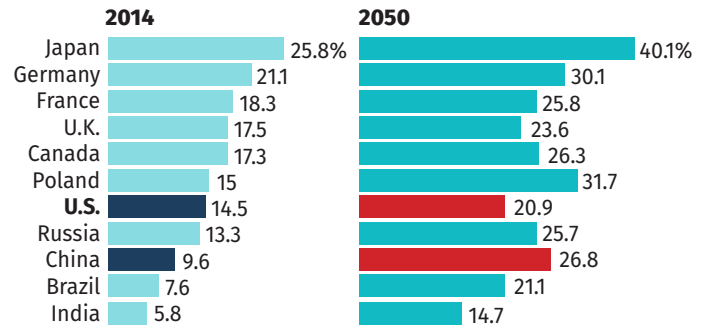
SOURCE: OECD, Kaiser

Three Global Drivers of Growth in Healthcare Spending

1) Aging Population

From 2010-2040, the population aged 60 years or over will increase 40% in developed countries, while the overall world average will increase by 300%.*

Share of Population Age 65 and Over



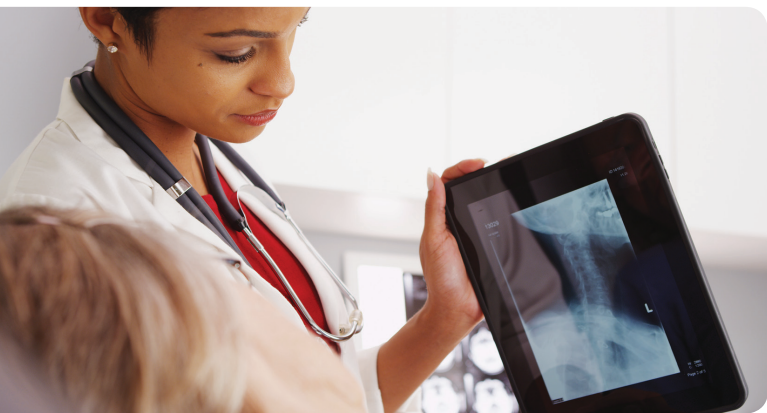
Source: U.S. Census Bureau International Database; U.S. Census Bureau International Data; *Deloitte (2015) – UN World Population Aging 2013

2) Emerging Market Countries

BRICs and MINTs are expanding access to health care to more of their citizens, which accounts for a rapid increase in national spending. The future annual rate of growth by value of all emerging markets' health care is roughly two to three times that of the 3% to 6% experienced in developed economies and is approaching the value of Europe's healthcare market (World Bank).

3) Modern Advances in Diagnosis and Treatment of Disease Are Highly Cost Intensive.

Over the past 30 years, technology has dramatically changed the way modern medicine is practiced and that has come with a cost. Hospitals have been transformed by advanced imaging and sophisticated surgical procedures into complex, industrial-like environments while the cost of biomedical research, clinical development, and regulatory approval of medical devices and drugs have also increased dramatically. In the United States, where medical costs are only partially regulated, healthcare spending is reaching an unsustainable level.



Global Health Care in Transition: Opportunities for Innovation

The rapid changes occurring in the global healthcare system require that the efficacy level of healthcare products and efficiency of service providers significantly improve. Key innovative technologies in health care are:

Personalized Medicine and Theranostics

For specific diseases, personalized medicine and theranostics involves the incorporation of molecular diagnostics coupled with targeted therapeutics to identify in advance those patients who will respond to a specific treatment based upon a genetic predisposition. While drugs are the initial focus, personalized medical treatments are tailored to the individual patient and can involve medical devices and other technologies.

Digital Health

An emerging field, digital health incorporates personal medical devices, genomic information, and remote monitoring capabilities to optimize an individual's healthcare delivery.

Telemedicine

Telemedicine is the use of telecommunications and information technology to deliver healthcare services remotely and typically involves a physician in one location delivering care to a patient in another location. This new delivery model has the potential to impact all key areas of health care. It expands access to modern medical treatment at a lower cost due to economies of scale.

Big Data

Involves the use of very large data sets generated from clinical practice and research for use in scientific or administrative application. Some examples are:

■ **Electronic Health Records/Electronic Medical Records (EHR/EMR).** EHR/EMR are digital medical records for patients that are accessible throughout their treatment by all healthcare providers. The aggregate data sets created in these records provide an opportunity for powerful computational correlation of information, including patient, disease, treatment, and outcome metrics that are being developed and used to determine best practices and to improve public health.

■ **Research.** EHR/EMR clinical information, combined with genomic and bioinformatics has the potential to drastically alter research and development protocols within health care and biosciences, from basic research to comparative effectiveness.



The Cost of Innovation

Research and development (R&D) are the engines that drive advancement and product innovation. The level or amount of R&D that an organization will invest varies widely based upon the industrial sector, customer market and the product itself. For a general industrial manufacturing sector, R&D spending as a percentage of total annual sales is in the 2% to 5% range, while a high technology computer and software firm might invest up to 9%. The health care/bioscience industry is the most research-based manufacturing business segment in the world.

In the global pharmaceutical subsector, investing in R&D for new drugs/vaccines by the top 10 companies averages 22% of their total sales. For the complementary medical technology/device subsector, the top ten companies spend 6% to 12% of total sales on R&D, with the amount based upon degree of complexity of the device.

All of this corporate investment is on top of the ~US\$100 billion spent by public, government, and academic institutions on biomedical research.

Drugs, vaccines, medical devices, and technology represent the intellectually based end product of immense investment over time, often requiring decades of work. This, along with the many failures at different stages of R&D, accounts for the high costs of healthcare products.

Global Top 10 Manufacturing Firms by Sector – Research and Development Spend

Manufacturing Sector	% of total sales spent on R&D	Average sales (US\$ B)
General Industrial	2-5%	\$200
High Technology	6-9%	\$136
Health Care		
Medical Technology/Device	6-12%	\$13
Pharmaceuticals	22%	\$43

SOURCE: Forbes, Financial Times, WSJ, FiercePharma

Manufacturing to Global Standards

The manufacturing of products for the healthcare field is one of the most demanding industries in the world. In virtually every country, government has dedicated staff whose job it is to make sure that international technical guidelines developed for the testing, approval, and manufacture of products are closely followed in order to ensure the safety and effectiveness of the product when administered to patients. Beginning with the material that a device or drug is made from, through each step of testing—from clinical level manufacturing through commercial product level scale-up—a very specific set of guidelines called current good manufacturing practices (cGMP) must be closely followed at all times, as required by national law.

In the case of pharmaceuticals, the active pharmaceutical ingredients (API) or active biological ingredients (ABI) must be manufactured to cGMP standards from the very beginning of human clinical trials through to the drug approval and

product manufacture. Any meaningful changes to the process of manufacturing, at any stage, have to be validated and approved by regulatory authorities for the purpose of making sure that the drug quality remains the same before the product can be sold and distributed to patients.



Innovation in Health Care/ Bioscience

Because of the scientific nature of most healthcare products, many start-up companies secure intellectual property and new technologies from universities, government or commercial organizations. At the company or academic level, staff work with researchers in securing the legal rights to the intellectual property and then in transferring, usually via licensing, the technology which has been created and is now ready for further development.

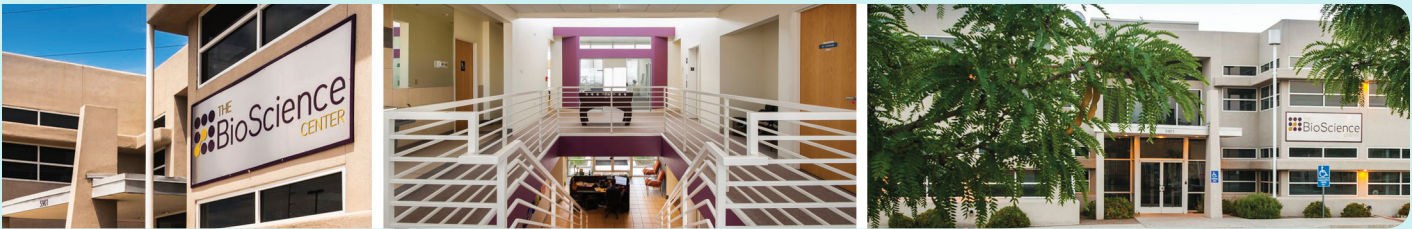
There are a variety of different start-up or incubator centers that assist young companies by offering key requirements for the initial phase of start-up:

- Access to initial capital
- Office and/or lab facilities
- Essential, cross-fertilization from technical staff and mentorship
- Support from industry experts
- Additional funding sources

Since R&D-based organizations require access to specific expertise and resources, governments often get involved in recruiting and directing similar companies into innovation clusters or entrepreneurial ecosystems in order to optimize and create an economy of scale. However, in the area of healthcare services, which often do not involve technical products, but rather the use of emerging and commonly available technologies in a unique application, the business model and requirement for start-ups are often purely entrepreneurial and less capital intensive.

Two U.S. Industry-Specific Incubators

The BioScience Center was founded and is managed by entrepreneurs who have considerable experience creating, nurturing, and exiting successful businesses. The Center occupies a 19,500-square-foot building in Albuquerque, New Mexico, providing offices, eight wet (chemistry and microbiology) laboratories totaling 2,500 sq. ft., and shared facilities that include reception, IT infrastructure, group purchasing, and conference space. The BioScience Center is not only a business incubator and accelerator, but also a centralized resource about biotechnology activity in New Mexico.



FatPipe ABQ was founded on the principal that start-up companies thrive in supportive environments where they can feed off each other, where collaboration, inspiration, and the sharing of ideas can happen on a trip to the copy machine or across the hall. FatPipe ABQ is located in a 10,000-square-foot facility in Albuquerque, New Mexico, and provides start-ups with furnished cooperative working space, multi-media equipment, information technology infrastructure, and a 300 MB “fat pipe” to the Internet, along with mentoring opportunities and connections to investors and potential partners.



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