美中生物医药协会会刊

CABA Connect

Chinese-American BioMedical Association Official Newsletter

Summer 2011
Volume 3, issue1

in this issue

CABA
P. O. Box 600241
Newtonville, MA
02460

A Message from the President

Dear CABA members and friends,

With great pleasure we present you this CABA Connect. Thanks to Dr. Qinglin Che and the editorial team for their dedication and hard work in bringing us another wonderful newsletter! CABA Connect documents CABA's major events and organizational matters. It helps connect us effectively and reach out more to serve this volunteer-based community!

Planted in Boston, the world's capital of talents and intellectuals and hub of biomedical innovations, CABA has grown into a well-established influential organization in only four years. Browsing through this issue of CABA Connect, you will notice that we firmly adhere to our missions: (i) to serve as a platform for our members to network and to help their career development; (ii) to serve as a bridge to connect our members with the scientific and business resources in China thus facilitating collaborations between US and China in the bio/pharmaceutical fields. Meanwhile, you will find that our events and activities are going in more depth and reaching out to broader professional and geographical areas.

Each year, CABA organizes three signature symposia: CABA's annual conference in spring; Innovation, Investment and Entrepreneurship Symposium in fall; and Medical Device and Diagnostics Symposium in winter. For each one, dedicated teams are set up ahead of time, high caliber speakers are actively sought after and invited, and agendas are thoroughly planned. On top of these three symposia, we set up special training programs and expert forums that provide members unique educational opportunities on topics of their interest. In summer, CABA Education Center organizes a pharmaceutical and medical device regulatory training program. This program is attracting a growing number of attendees and covering a wider range of topics.

Although CABA consists of professionals in biomedical field, CABA is also an organization that contributes to building a community full of fun. In summer, CABA organizes summer outing. Around the Chinese New Year, we organize Chinese New Year Gala together with 12 other professional organizations in Boston to celebrate Chinese tradition and culture. In the 2011 gala, we had great honor to have US senator Mr. Scott Brown (MA) who came to the gala in person to celebrate the Chinese New Year with the Chinese-American community and show his support.

As an organization built by members to serve members, we are extremely grateful that many more members are stepping up to help serve our CABA community. We now have 32 executive committee members and over 35 coordinators in addition to a dedicated legal council and 19 distinguished advisors, and we always welcome volunteers! With your active participation and support, together we can definitely build an even stronger CABA community!

Sincerely yours,

Chaoyang Dai, *Ph.D.*

CABA President 2010-2011

Zhihong Chen, *Ph.D.*

CABA President 2011-2012

Editor-in-Chief:
Qinglin Che

Volume Editors:
Li Xing, Ellen Fan, Jo Lee

Contributing Editors:
Regina Au, Ji Shi

Board of Publications:
Zhihong Chen, Qinglin Che, Chaoyang Dai, Jun Han, Yihan Wang, Zhao-Kui Wan, Junjun Wu, Zhiyong Yang, Phil Zhang

Photographers:
Jun Han, Zhonghe Li, Qinglin Che, Fred Hu, Chutze Chou

CABA CONNECT
Volume 3, Issue 1

Published by:
CABA
P. O. Box 600241
Newtonville, MA 02460 USA
www.cabaweb.org

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In This ISSUE

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Report on CABA 2011 Annual Conference

Biomedical Today: East Complements West

Reported By *Shengfang Jin, Ph.D., Director of Biology, Agios Pharmaceuticals Inc.*

The Chinese-American BioMedical Association (CABA) held its 2011 Annual Conference at the MIT Faculty Club on April 16, 2011, a sunny Spring day in New England with beautiful flowers blooming everywhere. It was an exceptional and timely conference considering the rapid redirection and exciting progress in Biotech and Pharmaceutical development worldwide. The program composed of diverse representations of the stakeholders, with key topics highlighted by examples from across the globe. Much to the credit of the annual conference organizers led by the Conference Chair and the President Elect, Dr. Zhihong Chen of Eisai Pharmaceuticals, and CABA President Dr. Chaoyang Dai, the invited speakers and guests represented prominent global players from biotechnology, health care, contract research organizations, academia, government agency, and pharmaceutical enterprises.

Titled "Innovation as the driving force", the first session of the conference was co-hosted by Drs. Shengfang Jin and Jinbo Lee. Energizing and inspiring participants in discussion, it set an exciting tone for the entire day. Mr. Duncan Higgons, Chief Operating Officer of Agios Pharmaceuticals, described Agios corporate strategy in his talk "Two PRCs – A New Strategic Axis". Extensive R&D collaborations were exemplified between Cambridge (People's Republic of Cambridge, PRC) based biotech and pharmaceutical companies and many P.R. China-based (PRC) organizations and institutions. The intimate and productive interactions between the two PRCs have completely transformed the way drug discovery is conducted today in the leading and fastest growing R&D hub of Boston. Going one step further on top of Mr Higgon's comments, Dr. Peter Mueller, the Chief Scientific Officer and EVP of Global Research and Development of Vertex Pharmaceuticals Inc., gave an outstanding lecture on "Chinnovation, an eye towards a future East-West health innovation network". Peter cited Chinese President Hu Jin-Tao's 2007 remarks "Innovation is the core of our national development strategy", and further explained that "Chinnovation = Value Innovation, … is applying changes in technology and business strategy to have new and better ways to create value for both customers and the corporation". Peter gave intriguing examples of how Vertex's Chinese collaborators have revolutionized Vertex's global strategic R&D networks in research areas including cystic fibrosis, tuberculosis, antibacterial and infectious diseases, as well as drug manufacturing. Peter delivered a striking concept of East-West innovation that has an impact on Global Health solutions. The idea resonated strongly with the participants. Vertex's Chinese collaborators and CRO partners played an instrumental role in advancing its recently approved anti-Hepatitis C drug telaprevir (INCIVEK ™). "Global Collaboration" has clearly become the norm in modern R&D, for which the second session, co-hosted by Drs. Qingling Che and Kevin Fang, provided a rich discussion of the key players and their transforming roles in the pharmaceutical industry. Richard Soll, Ph.D. SVP of Integrated Services, of Wuxi AppTech (Shanghai, China) talked about the "evolution of outsourcing from fringe activity to core, strategic partnership". He carefully depicted the important roles that oursourcing services provided to the mainstream pharma-

ceutical companies. During the coffee break, Richard remarked that with his second attendance to a CABA annual conference, he was "astonished by the seamlessly orchestrated activity throughout the day, the high quality speakers and diverse topics in line with mainstream R&D business". Richard's positive remarks were shared by several participants during the break, including Brad Prosek, Senior Director, Corporate Development of Cubist Pharmaceuticals, who highlighted the trend of traditional Chinese medicine entering the FDA-regulated clinical development process.

Considerable effort is underway for drugs that target the emerging market of China, with the mantra of "made in China and for China", including the development of liver cancer drugs. This is highly relevant to the fact that China is on track to become the world's third-largest Pharmaceutical market in 2011. In the first afternoon session "Research and Development Strategy", co-hosted by Dr. Yihan Wang and Ms. Ellen Fan, Pierre F. Dodion, MD, MBA, SVP, Business Development of ARIAD Pharmaceuticals spoke about the collaborative and strategic partnering opportunities between US- and China-based companies. He shared his experience in multi-centered phase 3 clinical trials in China. Afterwards an important update on the emerging strategy of applying disease biomarkers to facilitate patient selection and drug approval was highlighted in an interesting speech given by Joseph Eder, M.D. Senior Director, Clinical Discovery from AstraZeneca.

To access the drug market in China to the fullest extent, drug makers must list their products on the country's National Reimbursement Drug List, subject to Chinese FDA (sFDA) regulations. sFDA is largely regarded as still in its infancy in new drug approval and is heavily geared towards generic drug evaluation for historical reasons. One of the afternoon sessions touched upon the topic on "healthcare reform, emerging market, and sFDA regulation", co-hosted by Dr. Zhiyong Yang and Shiwen Lin. An sFDA Section Review Director and Visiting Research Scientist at the Harvard School of Public Health, Dr. Long Cheng gave a presentation entitled "regulation about clinical trial and registration of innovative drug in China" that highlighted the drug approval process from the vantage point of the under-staffed and heavily over-worked Chinese Regulatory agency. Clearly, the sFDA is beginning to reform its policy and process of conducting new drug approval. How will the healthcare reform in U.S. impact the Biotech/Pharmaceutical industry? Meredith B. Rosenthal, Ph.D, professor of Health Economics and Policy in the Department of Health Policy and Management at the Harvard School of Public Health, described the current status of health care reform measures and new directions. Meredith talked about the Patient Protection and Affordable Care Act (ACA) of 2010, which aspires to extend health insurance coverage to most U.S. citizens and legal residents, its coverage and delivery reforms. She projected new pressure for cost control from the Republicans and others as a result of the already huge and still rapidly growing national debt. All of these policies will impact the pharmaceutical industry to a great extent into the future.

The conference ended with an exciting session hosted by Dr. Zhao-Kui (ZK) Wan. The keynote presentation by Dr. Morten Sogaard, Executive Director & Head of Biotechnology, External R&D Innovation, Pfizer, was about "Pfizer External R&D - Towards the R&D Eco-System of the Future". Morten led an extraordinary discussion about the fast pace of change in the pharmaceutical world. He inspired the audience with facts and projections on important trends in the pharmaceutical industry, and shared his vision of better strategies for R&D in the future.

In addition to the stimulating presentations, the Annual Conference featured vendor shows, career fairs by US and Chinese corporations, and lunch and dinner networking events. Suvit Thaisrivongs, Ph.D, VP of Chemistry at Pfizer, remarked at dinner "this conference demonstrated tremendous organizational skills of the CABA society and the professionalism throughout the Association". His view is also shared by many participants at dinner discussions, including Chen Chen, Ph.D. SVP, of Sundia MediTech and Declan Ryan, Ph.D., Executive Director, Business Development of ChemPartner.

All participants agreed that the CABA 2011 Conference was an extraordinary success, covering the most important issues faced by many stakeholders in the pharmaceutical development and approval process. It provided an incredible networking platform for participants. We were all grateful to the speakers and our fantastic CABA organizing committee for putting together such a successful and rewarding event.

CABA Special Symposium

2010 CABA Investment Symposium and Hunan Biotechnology Innovation and International Exchange Conference

Reported By *Phil Zhang, Ph.D., J.D.*

The 2010 CABA Investment, Technology & Entrepreneurship Symposium & Hunan Biotechnology Innovation and International Exchange Conference was successfully held on November 20, 2011. It was a milestone event in the greater Boston area: the first time a signature community event was co-organized and held alongside a high-level business conference of a Chinese provincial government. Many dignitaries, guests and friends from both sides of the Pacific Ocean attended the event, including Dr. Ziying Fu, Vice Ministry of China's Ministry of Commerce and Dr. Lin Gan, Vice Governor of Hunan Province.

The event was attended by over 250 distinguished guests representing entrepreneurs, scientists, engineers, business executives, academics, professionals from financial and investment communities, and government policy makers. Distinguished speakers included Mr. McQuilken, Vice President of Massachusetts Life Science Center; Douglas Jensen, Ph.D., President & CEO, Spring Bank Pharma; William Li, Ph.D., President, Angiogenesis Foundation; John Piwinski, Ph.D., Site Head, Merck, Cambridge; Imran Nasrullah, CBO, MassBio; Tim Clackson, Ph.D., President/CSO of Ariad Pharmaceuticals; and Canwen Jiang, Ph.D., VP, Genzyme China.

The event also marked the fourth annual CABA Investment, Technology & Entrepreneurship Symposium, which over the years has become a major conference in the New England professional Chinese community.

CABA Special Symposium

2010 Medical Device & Diagnostics Symposium

Reported By *Ji Shi, MS; Wei Zhang, Ph.D.*

The CABA 2010 Medical Device & Diagnostic Industry (MDDI) Symposium was held on Saturday, December 4, 2010 at IBM Innovation Center in Waltham, MA. The theme of the event was "Bridging U.S. and China's Medical Device and Diagnostic Industry". More than 100 participants from the New England region attended the event.

As the second annual MDDI symposium, the event continued to function as an exciting platform for scholars, physicians, industry executives, entrepreneurs, consultants and legal experts to review industry trends/product innovations and discuss investment/start-up opportunities both in U.S. and in China. Compared to the pharmaceutical industry, products in the MDDI industry typically requires less up-front investment and shorter R&D period. Demand for medical device/diagnostics products are booming globally, especially in China.

The event was organized into three sessions, including Marketing/Business Perspectives, chaired by Ru Zheng from NECINA; Innovative Technology, chaired by Dr. Wei Zhang from CABA; and Panel Discussion chaired by Dr. Zhihong Chen form CABA. Speakers and panelist at this event included Xuan Kong, Ph.D., Vice President of Research, NeuroMetrix, Phil Zhang, Ph.D., J.D., Co-Founder and Co-Managing Principal, Milstein Zhang & Wu, Chris McFadden, MBA, Global Technology Program Director, Boston Scientific, Michael Drues, Ph.D., President, Vascular Sciences, Chao-Min Cheng, Ph.D., Post-Doctoral Research Fellow, the Whitesides Laboratory, Harvard University, William Lee, Ph.D., Director, R&D, AST Products, Inc., Steven Wu, MD, Director of Interventional Nephrology, Massachusetts General Hospital, Harvard Medical School, Jerry Zhu, Ph.D. M.D. Harvard Medical School, Jamie Li, Ph.D, Director, Urology/Women's Health R/D, Boston Scientific Corporation and Ji Shi, Senior Market Research Analyst, Boston Biomedical Consultants.

To cater to a broader spectrum of audiences in the region, the 2010 MDDI symposium was jointly organized by the New England Chinese Information and Networking Association (NECINA) and the American Chinese Medical Association (ACMA). Committee of the event consisted of CABA-members Dr. Wei Zhang, Dr. Zhihong Chen and Ji Shi; NECINA members Ru Zheng and John Xiaofeng Zhu (NECINA), and Dr. Jerry Zhu from ACMA.

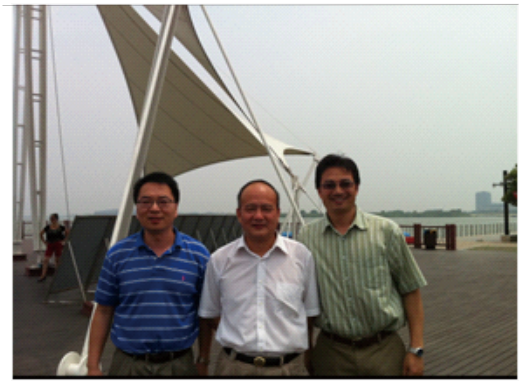
CABA China Report

CABA delegation to 2011 Wuhan Huachuanghui

Reported By *Zhaokui Wan, Ph.D.*

As one of a few high profile conferences, the Wuhan Huachuanghui has long established its brand in China. This year conference was held between June 26 – 28, 2011.

We were particularly attracted to the session of Biomedicine. In retrospect, this session in Huachuanghui was started by CABA and Wuhan sFDA in 2008. Most credits go to Drs. Yihan Wang and Shiwen Lin and Ms. Yan Li, Director of Wuhan sFDA for this significant initiative. Its rising influence has since gained much more attention from the field of China biomedical research as well as the oversea pharmaceutical communities as evidenced by the largest audience when compared to other sessions in the conference. For 2011 CABA delegation, it was led by Dr. Yihan Wang, Chairman of the Board.



▲ *Drs. Zhaokui Wan and Yihan Wang with Shanghai Linggang director Mi Shengjin.*

◀ *Drs. Zhaokui Wan, Yihan Wang, Zhihong Chen, Sue Ma visited Shaoxing, Zhejiang.*

For three years in a row, the Biomedicine Session filled in with many exciting presentations. Three seminars were chosen from CABA and its alliances this year. They were: Dr. Yihan Wang, Chairman of Board of Director, CABA, on "Review of Recent Progress for Targeted Therapy for Non-Small Cell Lung Cancer; Dr. Phil Zhang, Executive Director, CABA, on "Interface of FDA Regulatory Framework and Patent Law; and Dr. Wen Luo, President, SABAPA, on "Personalized Medicine and New Drug Discovery Platform".

In conjunction of Wuhan Huachuanghui, a CABA delegation, also led by Drs. Yihan Wang and Zhihong Chen, was invited to visit a few Chinese cities where biomedical research has become emerging. The cities visited are Shaoxing and Huzhou of Zhejiang Province, Wuxi of Jiangsu Province and Shanghai Lingang District.

华创会生物医药高峰论坛

2011 Wuhan Hua-Chuang-Hui Bioforum

2011年6月26-28日
中国湖北省武汉市

CABA China Report

CABA-Beijing Club Established on April 12th, 2011

The CABA – Beijing Club was recently established in Beijing to better serve CABA members who in recent years moved from the US to the Beijing area. 20 CABA members and guests attended the commencement meeting on April 12, 2011 in Beijing while CABA leader Drs. Yihan Wang, Chaoyang Dai, Zhao-Kui Wan, and Zhihong Chen participated in the live teleconference from Boston.

As a natural extension of the CABA organization, the CABA – Beijing club adheres to the missions of CABA to serve as a platform for our members in the Beijing area to meet their career development and professional networking needs and as a bridge to connect biomedical research, development, and business in the Beijing area and the US and other areas of China. The Club is under the leadership of CABA Board and its Executive Committee.

The CABA – Beijing Club members include Yueming Wang of Beijing Tide Pharmaceuticals, Eric Zhang of Beijing PharmacSciences, Lixin Jiang of Staidson (Beijing) Pharmaceutical Co. Ltd. and other "returnees" from the US. The club will host meetings, workshops, and social events to facilitate interactions among CABA members in Beijing. China clubs in other major biomedical hubs of China will be established accordingly.

Industry Trends and Updates

US Healthcare Reform, Generics and Biosimilars and the Affect on the Pharmaceutical, Biotech and Medical Devices Industries

Regina Au
Principal, Strategic Marketing Consultant, BioMarketing Insight

About the Author: Regina Au is a strategic marketing consultant for BioMarketing Insight specializing in the biotechnology, pharmaceutical and medical device industries. She helps companies evaluate their technology upfront to de-risk the product development process. Prior to BioMarketing Insight she worked for companies such as Merck & Co., Genzyme Corp., The Clinipad Corp. and NMT Medical. She had P&L responsibility in managing a number of multimillion dollar product lines and has experience in Product Development, Market Development, Marketing Strategies, and Product Launch. Her background includes an MBA in Marketing from the University of Connecticut, a Microbiology degree from the University of Michigan and a Masters in International Management from Thunderbird School of Global Management.

PART I. Pharmaceutical and Biotechnology

The proposed Healthcare reform for biosimilars will have a major negative impact on the pharma and biotech industry because biologics are more costly, time consuming and requires a longer lead time in commercializing a product than pharmaceutical drugs.

Generic drugs are approved on equivalent bioavailability and not efficacy since the chemistry is straightforward. The big debate is the FDA regulatory pathway for biosimilars. Some argue that "because the biologics are made from living cells, and the manufacturing processes are so complicated, new clinical trials are needed to ensure purity, potency, and safety."

Three Critical Challenges for the Pharmaceutical and Biotech Industry

Generics drugs have always been a "thorn in the side" of the pharma industry because of revenue loss and pressure to launch new products to make up for this revenue loss. Pharma companies have expanded to include biologics in their product portfolio which are more costly and time consuming than drugs.

Right now the pharma industry is in a quandary because a number of billion dollar blockbuster drugs and biologics are going off patent and there are few new products in the near future. The proposed healthcare reform on biosimilars is yet another thorn for current and pipeline products.

The EU has already decided to have two separate regulatory pathways, one for generics and one for biosimilars and each type of biosimilar will be considered separately.

Two critical pieces of the proposed US regulatory requirements will determine whether the pharma or biotech companies will be able to survive in this industry.

1) Is it twelve years of data or market exclusivity or both?

President Obama signed the Patient Protection and Affordability Act that granted manufacturers of brand name biologics 12 years of exclusivity before biosimilars can enter the market.

The heated debate according to the Wall Street Journal is between the healthcare payers and the drug developers on the definition of exclusivity. Payers interpret the exclusivity as 4 years of data exclusivity and 12 years of

market exclusivity allowing generic companies early access to the developer's data in preparation of launch in year 12.

Drug developers interpret the bill as 12 year data exclusivity where generic companies would not have access to their data until year 12 thereby delaying generic entry. This would also allow developers time to recoup their R&D costs. "Congress intended data exclusivity to be an incentive for innovation," said Amgen, which makes several top-selling biologics.

The lawmakers are split between the two parties. Three Democratic senators, Sherrod Brown of Ohio, Tom Harkin of Iowa and Charles Schumer of New York, and Republican Sen. John McCain of Arizona agree with the generic drug makers and healthcare payers.

The principal authors of the bill who were striving to "balance incentive for innovation" and agree with the drug developers, created the approval pathway for 12 year data exclusivity. "In a letter sent last month, Reps. Anna Eshoo (D-Calif.), Jay Inslee (D-Wash.), and Joe Barton (R-Texas)... "express concern that FDA officials are confused about the 12-year period of data exclusivity that was granted to manufacturers of brand biologics when President Barack Obama signed the Patient Protection and Affordable Care Act into law last year."

"Who's right? Neither side, generic drug lawyer Kurt Karst of Hyman Phelps & McNamara PC tells the WSJ." The law doesn't specify and Congress will have to settle yet another biosimilar debate.

2) Will clinical trials be required to demonstrate safety and efficacy?

"What makes biologics different and more expensive?" Anna Eshoo (D-Calif), the principal author of the bill comments "Biological products are fundamentally different. A biologic is a large, complex molecule, which is 'grown' in living systems such as a microorganism, a plant or animal cell. The resulting protein is unique to the cell lines and the specific process used to produce it, and even slight differences in the manufacturing of a biologic can alter its nature. As a result, biologics are difficult, sometimes impossible to characterize, and laboratory analysis of the finished product is insufficient to ensure its safety and efficacy."

"Even if a biosimilar is proven to be safe and effective, it will likely still have different properties than the original innovative product. There may be differences in dosing, different side affects or safety profiles, and differences in effectiveness for certain diseases or patient groups," said Anna Eshoo.

"What differentiates this market is that it's a much more expensive process to make biologics. You need bioreactors, cell banks, lots of specialized equipment," said Don Ware, the Boston-based co-chair of the life sciences division at law firm Foley Hoag LLP.

Generic companies are currently targeting blockbuster monoclonal antibodies (biologics) developed by the top biopharma companies. "But it won't be cheap. The research group Collins Stewart has estimated that developers will need to budget $100 million for the kinds of clinical trials that will be required to gain an approval. And once they hit the market, the follow-ons are expected to offer discounts of 10 to 15 percent."

3) How did a biosimilar get approved through the current regulatory pathway?

Momenta/Sandoz Pharmacueticals, the generic arm of Novartis have cleverly figured out a way to obtain approval for their biosimilar of Lovenox, made by Sanofi-Aventis using an alternative regulatory pathway currently in place for years. Pharma and Biotech companies are now scrambling to figure this out how they did it and how to protect themselves.

"Our advice (to companies with name-brand biologics) is to think about creating a broad patent portfolio, not only to cover the sequences of molecules, but more importantly, also protecting the method of formulation, the dosing, the delivery methods," said Jonathan Sparks, a Boston-based attorney in the life sciences practice at McCarter & English LLP. "You need to create a picket fence around the product."

Recommendations

There are three things that a company with a branded biologic can do to slow the entry of biosimilars: 1) have a broad patent that covers the sequences of molecules, but more importantly, the method of formulation, the dosing, the delivery methods according to McCarter & English LLP, 2) develop better biologics where sequence, methods of formulation, and delivery methods are difficult and cost prohibitive for generic companies to enter the market and 3) petition vigorously for 12 years of data exclusivity and clinical trials to prove efficacy and safety.

"If you can't beat them, join them" seems to be the sentiment since the US biosimilar regulatory pathway was proposed, the implementation of biosimilars in the EU, and the successful launch of a biosimilar for Lovenox by Sandoz/Momenta. Many major pharma companies have entered into the biosimilar market including, Pfizer, Merck, Spectrum, and Endo in addition to "generic" companies Teva and Watson that are not part of Big Pharma.

This allows Big Pharma with brand biologics to recoup some revenue vs. no revenue when biosimilars are purchased. It's easier for Big Pharma companies to enter the biosimilar market if they already manufacturer a

branded biologic. It's another source of revenue that only requires about a tenth of the R&D budget of branded products for those entering the market.

As companies enter the biosimilar market copying branded biologics from other pharma companies, it's going to be an enormous battle for market share. The gains are short term because price is the only driver compared to name brand biologics (before generics) that offer compelling benefits. The companies that enter the US and EU market first (projected discount of at least 10-15%) will have the biggest rewards, but then they dramatically drop as each competitor enters the market. The biosimilar market looks very appealing, but I caution that the industry does not take its focus away from innovation in regards to time and money.

Biosimilars is another avenue of getting into the emerging markets as mandatory discounts are at least 40% as mentioned in my January newsletter. But the regulatory pathway will determine whether it will be a worthwhile venture. Many major pharma companies have already made significant acquisitions of local pharma and generic companies in penetrating these markets including Teva Pharmaceuticals, a generic company that is aggressively pursuing emerging markets.

PART II. Medical Device

The regulatory pathway for generics in the medical device industry is simpler, barriers to entry are much lower, and the resulting product is often of lower quality than brand name devices. And now, to add insult to injury, the new healthcare reform dictates four challenges that would allow generics early market entry and discourage innovation.

Four Challenges for the Medical Device Industry

1) FDA 510(k) Approval Process

One of the methods the medical device industry has tried to combat generic devices is to develop new devices or improve the current device. But, one of the biggest obstacles for the medical device industry is the lengthy 510(k) approval process for new or improved devices due to the complex, cumbersome guidelines, closed communication with the FDA and being understaffed.

The FDA has proposed to implement changes to deliver "a smarter medical device program that supports innovation, keeps jobs here at home and brings important, safe and effective technologies to patients quickly," said CDRH chief Dr. Jeffrey Shuren.

On January 19, 2011, the "FDA reveals plans to implement 25 changes to its 510(k) medical device clearance program, but will hold off on any major moves until after the release of an Institute of Medicine report that is scheduled for this summer."

"The Center for Devices and Radiological Health said it would also implement changes including streamlining the "de novo" review process for lower-risk devices, clear guidelines on when medical device manufacturers must submit clinical data in a 510(k) submission and the creation of external experts who can use their knowledge and experience to help the agency address important scientific issues regarding new medical device technologies by Sept. 15."

"About half of the 55 changes the agency recommended in August 2010 are still being discussed. Among those were several of the most controversial elements, such as the ability to revoke 510(K) clearances, increased post-market surveillance, and the establishment of a new classification (Class IIB) for medical devices that would require the submission of clinical evidence. "

2) Transparency

To bolster the safety of medical devices, the CDRH has proposed the following:

1) "Establish a public database of important device information, such as medical device photographs, labeling and summaries of the basis for the FDA's decision to clear specific devices. The database will be discussed at a public meeting taking place April 7 and 8, 2011."

2) "Require a brief description of scientific information regarding the safety and effectiveness known to the manufacturer for select higher-risk devices on a case-by-case basis through device-specific guidance."

These proposals that require a public database for transparency would allow competitors to copy the inventor's device and discourage innovation. It's not surprising that the medical device manufacturers are having a negative reaction to it.

"Everything you submit - your CAD, your drawings, your engineering, your indications for use, your clinical studies, all the mistakes you've learned - will be disclosed for all the world to see," (Michael) Minogue, CEO of Abiomed said. "This would really be detrimental to innovation and would really punish the smaller companies. It will slow down people investing in big bets and the learning curve will basically be cut away from the innovators. And it will likely be a great source for foreign companies to download and look at everything we have on the road map. Transparency might not be (what) they're looking for...when you really think about what it could do to innovation in the States."

3) Device Tax (2.3% tax) on revenue

The healthcare reform has mandated a 2.3% tax on medical devices in generating $20 billion dollars to help pay for health insurance for all Americans. This tax will have a detrimental impact on the industry leading to a loss in revenue, loss of jobs, decrease R&D budget that discourages innovation, decrease in employee benefits, and an increase in outsourcing overseas.

"MDMA is very concerned about the impact ...on patient care, innovation and small business.... Under the current structure, many companies will owe more in taxes than they generate in profits, requiring companies to layoff employees, cut R&D budgets and slow the development of new therapies that would have improved the quality of care for all Americans..." said Mark Leahey, president and CEO of the Medical Device Manufacturers Association.

On January 27, 2011, four Senate Republicans revealed a bill that would eliminate the medical device tax scheduled to go into effect in 2013. "A $20 billion tax hike on medical device manufacturers to fund Obamacare will cripple an important engine of opportunity, job growth and innovation, while hurting the advancement of technologies essential to improving patient care," Senate Finance Committee ranking member Orrin Hatch (R-Utah) said in a statement.

4) Decreased CMS reimbursement

The healthcare reform includes reducing the budget for CMS (Medicare/Medicaid). The 2010 fee schedule dramatically reduced payment to device manufactures in several therapeutic areas. A few examples are:

1. Cardiac device: 30-40% fee reduction

2. Pelvic CT: 48% reduction in nonhospital setting

3. Chest Spine: MRIs 46% reduction

The 2011 fee schedule updates are currently not available. But if the dramatic reduction in reimbursement continues, this will definitely discourage innovation in the US, encourage innovation to be outsourced overseas or encourage innovation for emerging markets.

Recommendations

The best method for device companies with brand name products to protect themselves is to have a broad patent that not only covers the design of the product but all applications.

The device industry has multiple obstacles with the existing cumbersome and lengthy 510(k) regulatory process, proposed transparency, tax on device and significant decrease in reimbursement. The device industry must continue to aggressively lobby for a streamlined 510(k) process, an elimination of transparency and device tax, and a stabilization of reimbursement in order to survive this current economic environment.

If reimbursement continues to be significantly decreased, the medical device companies will stop innovating for the US. It will drive devices manufacturers to emerging markets where low technology devices are needed since the infrastructure can not accommodate sophisticated technology and trained professionals are needed to perform or interpret this technology. The requirements to consider when developing low technology for emerging markets: 1) its inexpensive, 2) no assemble required, 3) very easy to use, 4) easy to transport regardless of the climate conditions, and 5) no interpretation required for results.

Discussion of innovation going overseas has already started as the US healthcare industry announced at the end of January that it will "work more closely with its Chinese counterpart under an initiative launched to improve innovation of drugs and devices in both countries through public-private partnerships. The initiative was part of Chinese President Hu Jintao's state visit to the U.S., which included 12 U.S. companies, six supporting organizations, and government agencies from both countries. Pharmaceutical and device companies that will participate include Abbott, J&J, and Pfizer."

For more information or questions regarding this article, you can contact Regina Au at regina@biomarketinginsight.com or for additional articles on the current trends and activities in the industry, visit http://www.biomarketinginsight.com/News.htm

BioMarketing Insight helps companies de-risking their product development process by evaluating their technology upfront. We conduct the business due diligence to ensure that it is the right product for the right market and the market potential for the product meets the business goals of the company. We can then develop marketing strategies to drive adoption for the product.

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CABA Education Center News

美中生物药协培训班毕业礼

2011年9月27日星岛日报记者菊子波士顿报道

美中生物医药协会 (CABA) 上周末在麻省理工学院 (MIT) 举办专家论坛暨药监法规培训班毕业典礼，辉瑞制药公司副总作专题论谈，大会欢送四名武汉市食品药品监督管理局学员学成归国。

美中生物医药协会 (CABA) 药监法规培训班承办负责人林世文 (右起)、学员祝红丽、刘杰、姚盛、黄桦、王义汉、SuvitThaisrivongs 副总、段建民 (前左四)、Shire 制药公司资深法规主任宇文镐 (后左一) 等人，兴高采烈出席讲座及毕业典礼。
菊子摄

辉瑞制药公司免疫及自动免疫医药化学主管 SuvitThaisrivongs 副总当天应邀讲谈「医疗挑战及制药研究创新」。毕业于哈佛大学、加州理工，以及瑞士联邦学院 (Swiss Federal Institute) 的 Suvit Thaisrivongs 博士，有 28 年的制药研究经验。他所领导的研究小组在心血管疾病、传染病、中央神经系统、发炎、免疫、过敏及呼吸系统、肿瘤等领域，曾找出许多候选药物。他也是 tipranavir（APTIVUSR），HIV 蛋白酶抑制剂抗爱滋病药物发明者。SuvitThaisrivongs 指出，医药界目前面对的一大挑战是，用作测试药物的老鼠，对药物反应的通路 (pathway) 和人类并不一样，因此用老鼠做针对某种病毒的治疗传染病测试，还能有效，慢性病就不见得有用了。Suvit Thaisrivongs 博士透露今年十月下旬，他将赴圣地牙哥，出席医疗化学会议，讲谈「激酶 (kinase) 药物研发」。

今年是美中生物医药协会第三年为武汉市食品药品监督管理局举办为期三个月的培训班。为加强中美医药业界交流效果，该培训班今年还对本地 (BOSTON) 业界人士开放报名，共有 BiogenIdec 的祝红丽、AceBright、AstraZeneca、Synta 等制药公司的雇员及在美度假的吉林农业大学教授马吉胜等六人，一起上课。

来自武汉市的食品药品监督管理局青山分局副局长黄桦，稽查分局副主任科员的段健民，以及副组长姚盛，科员刘杰等人，当天都做了报告，展示他们的学习成果。他们也表示，在培训期间到波士顿科学公司 (Boston Scientific)、辉瑞、Biogen Idec，诺华，Genzyme 等大公司及顶级医院 MassGeneral 及哈佛医学院系统参观，的确收获很多。

黄桦谈及中美两国在实地稽查上的差异。她表示，整体做法上差不多，但美国的联邦药品管理局 (FDA) 的稽核，事前做例行审批，事后视不同原因做审批。大都由地方办公室执行。中国则分有国家、省、市、地区不同层级的食品药品监管局。美国有六种检验体系，至少对其中的四种做完整检验，另二种做简略检验，但品质检验一定包含在其中。美国 FDA 注重检验文件及记录，中国的国家 FDA 注重实地监督，对生产场地、实验室、使用中的仓库等，有不下十二方面的特别关注。美国 FDA 的一名检验员，平均一年只负责检验十家公司。中国的药监管理检验员，一年要检查一百家以上企业。美国 FDA 发警告信，要求符合法规。中国药监也给警告，并负责征收罚款。美国 FDA 会公布执行结果。中国不公布。

黄桦指出，武汉市药监局有六百多名员工，每年选送人员进修，对提升该局的整体作业，和国际接轨能力，很有帮助。

中美知识产权法律师协会 (CAIPLA) 创办人张引，CABA 会长陈志宏、董事会主席王义汉等人，当天都出席交流。

武漢食品藥品監管局MIT講座

2011年8月30日星岛日报记者菊子剑桥市报道

武汉市食品药品监督管理局专业培训团 2011 年 8 月 27 日经培训团承办单位美中生物医药协会 (CABA) 协助，在麻省理工学院 E51-315 教室举办讲座，介绍武汉光谷生物城崭新面貌，畅谈生物医药及医疗器械产业前景广阔，重申武汉 3551 人才工程可拨给一流创新团队最高一亿元资金支持的优惠。

武汉市食品药品监督管理局青山分局副局长黄桦在会中重点指出，中国医疗器械业现在年产值约 1000 亿元人民币，相当于医药业 30%。以中国境内现有约 14000 家医疗器械制造商，绝大部份制造低端产品的情况来看，这领域的未来发展潜力极大，中国政府也计划在基层医疗设备，以及医疗保险改革所需设备上，投资 850 亿元人民币。黄桦说，中国政

府为在武汉光谷生物城推动企业发展，吸引人才，已设立了 100 亿元人民币的生物光谷创投基金，并正藉由 3551 项目，每年投资一亿五千万元人民币，引进高层生物及新兴产业专业人才与团队。对于可领导产业发展，带来重大效益的世界一流创新团队，最高给予一亿元的资金支持。由于医疗器械的审批时间比药物快得多，以及政府为帮助农村获取基础医疗设施，订有不少新法规，黄桦提醒与会者充份利用第一类产品报批，在武汉市五天内就可审批出来，速度是全中国最快的这一优势，在武汉生物医药领域发掘创业机会。

◀ 会中提问、讨论情景。菊子摄

美中生物医药协会 (CABA) 武汉药监局培训班负责人林世文（前右起）、学员段健民、姚盛、武汉药监局青山分局副局长黄桦、CABA 曲芸、祝红丽、范一林、田泽；武汉药监局科员刘杰（后右起）、CABA 前会长万昭奎，CABA 董事会主席王义汉等人会后合影。菊子摄

黄桦当天介绍了武汉市备具九省通衢，国家创新型试点城市，以及内有高铁，可在四小时内抵达北京、上海、广州、成都等大城市，是国内第四大航空港等地理优势，说明武汉市食品药品监督管理局的职责，不但包括药物审批，进口药物备案，还得承办监管餐饮业的食品安全卫生，为有意进中国发展生物医疗企业者提供资讯与服务等。当天黄桦特地放映了一段武汉光谷生物城最近才制作完成的一辑新介绍影片，展现出光谷已于 2010 年内，陆续有华大基因、药明康德与武汉国家生物产业基地建设管理办公室签定合作协议，辉瑞制药公司在园内成立武汉研发中心，占地 1700 亩的医疗器械园、占地 6300 亩的生物医药园陆续开工等一连串新发展。园内的最新动态包括投资金融超市开业，国家新药孵化基地获批等

武汉市食品药品监督管理局敦请美中生物医药协会办理，由林世文等负责的专业培训团，已办了三年，每年培训四至六人，期以提升该局职工的专业水准，也借机促进中美交流。今年来波士顿参加培训的有四人，包括于去年十二月中起上任为青山分局副局长的黄桦，于去年十月上旬上任为稽查分局副主任科员的段健民，以及副组长姚盛，科员刘杰等人。

当天出席讲座者，在药物审批，研发等的相关规定上，向前述四人提了不少问题。在无锡获千人计划奖，创办了迦俐申生物医药 (CallisynBiomedical) 科技公司的姚飞，当天正好在波士顿，也特地出席和本地生医领域人士交流，顺道进一步了解向他招手的武汉概况。

美中生物医药协会 (CABA) 武汉药监局培训班负责人林世文，该会现任会长陈志宏，董事会主席王义汉，历任会长万昭奎、戴朝阳，以及承办培训班工作的曲芸、田泽、范一林，以及本地学员祝红丽等，当天也全都到会。

远渡重洋借他山之石，横跨亚美架沟通桥梁

武汉市的食品药品监督管理局　刘杰

2011 年 7 月 5 日，武汉市食品药品监督管理局赴美培训第三批成员一行 4 人抵达 Boston，开始了为期 3 个月的学习。美中生物医药协会（CABA）具体承担相关培训事宜。

为了不断提高对于食品和药品的监督管理能力，充分保障国民饮食用药安全，武汉市食品药品监督管理局的领导高瞻远瞩，充分认清到中美之间在食品和药品监管理念、能力以及取得成效方面存在的现实差距，从人才培养的长远角度考虑，毅然决定挑选人员派赴美国学习，在 2009、2010 年先后派出 2 批学习小组并取得圆满成功的基础上，今年又派出了以分局副局长黄桦（Susanna Huang）带队的第3批学习小组，一方面继续加强对美国 FDA 先进监管理念等知识的学习，以期开阔视野，回国后将学到的知识与实际工作相结合，不断地增强业务素质和能力，更好的为国民服务；另一方面，也要加强相关的宣传与推介，努力提高 Boston 相关行业和人员对武汉市的了解，为促进中美之间的沟通与交流架起一座友谊

美中生物医药协会（ＣＡＢＡ）负责本次培训，他们既为培训小组安排了丰富而又具有针对性的课程，又对他们的生活给予了充分的关心。

7月10日上午，ＣＡＢＡ为学习小组的到来举行了欢迎仪式，会长陈志宏先生，董事林世文、王义汉、万昭奎、车庆林、Wendy, Susan, Ellen 等出席了活动，通过愉快的交流，双方都表示将加强沟通与合作，共同努力，保证本次培训活动取得圆满成功。

美中生物医药协会媒体新闻汇编

CABA in the Media

美中生物醫藥協會年會搭中美橋樑

星岛日报记者 周菊子 波士顿报道

美中生物醫藥協會 (CABA) 十六日舉辦年會，強調中美交流，中西醫藥互補。陳志宏、戴朝陽兩名新舊會長在二、三百名出席者祝福中完成交接，報告該會向東發展，已佈點北京，正邁向武漢。

CABA 在麻省理工學院教授俱樂部舉辦的年會，主題為「生物醫藥行業前景展望：機遇和挑戰 (Biomedical Today: East Complements West)」，共邀有近廿名中西學者、專家及業界高管分享經驗，暢論醫藥界所面對問題，包括醫療保險改革對製藥業的影響，業界採用那些方法因應，中美公司怎麼合作找機會，來增加生產效益等，包括邀請目前在哈佛大學公衛學院訪問學者程龍講談中國藥物監管制度與規定，哈佛大學公共經濟及政策副教授 Meredith B. Rosenthal 講談美國醫療改革對製药業的影響。

新任 CABA 會長陳志宏指出，ARAID 製藥公司資深副總裁 Pierre F. Dodion 在講座中談及，該公司藉 CABA 幹部協助進中國做治癌藥臨床試驗，進展順利，近期內可能獲得美國藥監局 (FDA) 批准，就是該會這類會議發揮的作用。

卸任會長戴朝陽在卸任報告中說明，該會目前有活躍會員逾千，顧問廿名，執委 32 人，去年辦過不下四場和全美化學協會東北分會等合作的大型會議，數度接待北京投資局辦招才攬商會，也組團參加或協辦了不下五場在中國武漢、上海、廣州等地舉辦的大型會議。北京泰德製藥副總經理王月明已獲選為 CABA 北京俱樂部負責人。該會也正籌組武漢俱樂部。

CABA 董事林世文也在會中報告，該會今年七至九月將續辦「中國藥監局管理人員培訓班」，有心瞭解中國境內藥品監管規定變動者，可利用時間交流。

CABA 的這一年會，綜論了「創新做為驅動力量」，「全球合作」，「研發策略」，「醫保改革，新興市場及藥監局規定」，「全球合作，研發策略」。Vertex 製藥公司全球研發資深副總裁 Peter Muller 在「創新做為驅動力量」的講座中，借用了新加坡南陽大學客座助理教授陳英嵐所寫的「Chinovision」一詞，侃侃而談他個人在中國的經驗與觀察。他指出，「Chinovision」這篇文章總結了中國式創新的八個 R，包括營收 (Revenue)、快速 (Rapid)、靈活迎合顧客 (Requirements)、複製 (Reproduce)、對手 (Rivals) 競爭壓力大、對臉書 (Facebook) 之類公司的限制 (Restrictions) 入境、重新整合 (Remix)、非實體的原材料 (raw materials) 眾多等等。

陳志宏表示，Peter Muller 特地點出了中國創業家密集，高科技人才及風險投資基金充沛，購買力強等現象。包括全球創業觀察 (Global Entrepreneurship Monitor (GEM) 報告指出，中國有 4% 的工齡人口從事期望高成長創業活動，美國卻只有 1.5%，以及單只是中科院，每年就有不下十萬名博士生畢業等。2009 年內，中國境內經辦的風險投資，不下 420 宗，金額高達 27 億美元，消費品零售額達到 12 兆人民幣。

輝瑞製藥公司的外部研發創新部生物科技執行主管 Morten Sogaard 是 CABA 年會的晚宴主講人。他講談了製藥業未來的研發生態系統。輝瑞公司的外部研發創新部全球生物治療科技主管李躍進 (Luke Li)，當晚也出席到會。

哈佛大學醫學院 McLean 醫院副教授 (Associate Professor) 李豫偉這天在會中介紹了「用傳統中藥治骨關節炎」。他指出，在 2011 年內，治療骨關節炎藥品的市場，約可達二百億美元，但目前市面上可找到的西藥，其實還不如早從中國黃帝內經及本草綱目傳下來的中醫藥有效。

只是中藥得用十一種草藥調配，產地及種植情況也影響藥效品質，。他和夥伴成立的一家公司，目前在中國培育草藥，2007 年四月已通過第一階段的臨床試驗。他相信未來十年是傳統中醫的黃金年代。

麻州参议员捧场2011华人春晚

多维新闻 王铴 撰稿

由 14 个新英格兰华人团体联合举办的第三届新英格兰华人专业人士春节联欢晚会及社区论坛 2 月 13 日隆重举行，吸引了超过 500 名个专业领域的华人到场。随着华人地位在美国的提高，此次活动受到了包括麻州参议员、州长在内的 6 名政要的贺词与参与，表现出对华人社团前所未有重视与支持。大会主办方美中生物医药协会的会长戴朝阳向多维新闻表示，此次麻州政要对此次活动的重视，表明了华人社区活动影响到了美国主流社会。对华人的重视表明了华人对美国主流社会的影响。

布朗与驻纽约总领事彭克玉及麻州华人社团领袖合影

共和党参议院布朗（Scott Brown，R-MA）作为此次春晚的主讲人，首次以参议员的身份在公开场合表示自己将联合加州民主党参议员范因斯坦（Dianne Feinstein，D-CA）要求国会向排华法案道歉，并对华人专业人士对麻州的经济做出贡献表示感谢。

民主党参议员克里（John Kerry, D-MA）发表书面致辞，表示这次活动在传承中国文化的同时，是华人社区和个人力量的见证。多年来华人专业人士在提高个人能力的同时，为华人社区做出了贡献，创造了未来更好的商机。

麻州州长帕特里克（Deval Patrick）、副州长莫瑞(Timothy Murray)、麻州财长格罗斯曼(Steve Grossman)、麻州剑桥市华裔市议员张礼能(Leland Cheung)都向此次活动发表贺词。

美中生物医药协会的副会长车庆林向多维新闻表示，在与麻州各政府官员联系的过程中，收到了非常积极的反馈。此次活动不仅给予了个专业领域华人提供了一个不可多得的全面的沟通交流的机会，促进各专业领域的互动与反馈，更为重要的是，此活动显示出了麻州华人的力量，并与美国主流社会联系起来，意义非凡。此次活动由新英格兰地区 12 个华人专业人士团体联手，并携波士顿中国校友会联合总会加盟，奉献给参与者一组别开生面的庆祝活动，囊括了专题讲座、文化沙龙、就业咨询、文艺表演、鸡尾酒会、浪漫晚餐、交谊舞蹈，和卡拉 OK 等活动。到场的中美专业人士包括了律师、医生、会计、科学家、工程师、企业家、金融家、艺术家、政治活动家等。

其中专题讲座包括了首届波士顿亚裔健康会议作举办的医学论坛，纽约总领事馆参战毛中颖、中国与全球文化研究中心主任王辉耀博士就海外华人机遇发表演说。文艺节目则呈现给观众京剧、中华武术、藏族舞蹈等别具中国特色的精彩演出。

此次活动的主办单位包括了北美中华医学会、美中生物医药协会、中美知识产权法律协会、128 华人科技企业协会、麻州香港协会、MIT 华人科技学会、MIT 经济与人才论坛、纽英伦中华资讯网络协会、留美华人企业家协会、纽英伦金融及會計泛亞領袖會、美洲华人生物科学学会、全美华人金融协会，协办单位包括波士顿中国校友会联合总会和中国人民大学附属中学海外校友会。

北京投資局再訪波士頓

星岛日报记者菊子报道

北京市投資促進局日前又訪波士頓，並在美中生物醫藥協會（CABA）協助下，舉辦「北京—波士頓生物醫藥產業合作及引進優勢項目洽談會」，再度吸引了五、六十人出席。

北京市投資促進局這趟的訪波團，仍由局長周衛民領隊，隨員包括副局長周旭，產業促進處副處長高節，服務貿易處副處長張華雨等人。

周衛民當天以「北京經濟發展、重點產業及資源優勢」為主題，再度侃侃而談中國情勢大好，在改革開放三十年後，必還再有三十年的黃金發展週期。目前中國、北京都有錢，缺的是好項目、好人才。

北京市投資促進局率團訪波，美中生物醫藥協會協辦洽談會。左起為王一愷、王義漢、周旭、萬昭奎、周衛民、胡永韓、張華雨、高節、林世文等人。菊子攝

周衛民為強調與政府，尤其是中央政府合作的好處，還以比爾蓋茲 (Bill Gates) 為例，指美國政府當年調查微軟是否壟斷市場，讓微軟瞭解到和政府打交道的重要性，立即成立政府關係部門 (government relations)。既然在美國和政府合作都那麼重要，又何況是中國。從事生物醫藥業的，可能都得和藥監局、發改委打交道，關係建立得好，就會知道怎麼樣填寫申請報告書，申請上千萬元的補助經費。

周衛民隨即補充說明，建立關係當然得在廉潔自律的限制下進行，他可沒鼓勵大家搞腐敗，惹得台下一陣哄笑。

他接著笑談中國的兩大短信龍頭，騰訊和 QQ 震動全中國的相持不下，最後也是在北京政府「再不停止爭鬧，就勒令歇業」的一聲令下後，不到 24 小時就消瀰於無形。

在周衛民的報告中，中國有 6+1 的經濟發展推動力，包括工業化、城市化、市場化、信息化、全球化，世界製造中心，以及自主技術創新等。他也指出，中國是全球唯一的一個國內市場容量大、增長快，綜合成本卻仍低的國家。進中國投資企業，發展潛力更大。

他也以「北漂」為例，指藝人、明星等時尚一族，常也總要先到北京轉一圈，獲得具有消費示範的北京「認可」，才紅得起來。

周衛民這天還重提了北京具有八大優勢，在吸引、扶持生物醫藥產業上，北京訂定了五大措施來引進國內外重點企業，包括要引進投資額不低於兩億元人民幣的內資企業；投資額不低於五千萬美元的外資企業等。目前全北京市已認定 620 工程企業 39 家。凡是獲認定為 G20 工程的生物醫藥企業公司，北京市府將投資入股，並允諾三年後只收取投資本金及活期存款利率就退股，期間還負擔國及市級的重大科研項目資金，產業化的無償扶持資金等。

在侃談、回答問題時，周衛民也無法避免的遇到房價問題。他認為房價雖然在調整中，但在人口壓力及城市化造成的需求下，北京房價將來恐怕仍會上漲，經該局進北京的企業人才，卻可享有「戶口」，以及買房的資格。

北京市投資促進局此行再度從加州到波士頓，加拿大走了一圈。日前的這場洽談會由 CABA 常務理事胡永韓主持。該會董事會主席王義漢，曾任主席的萬昭奎等人協調。包括參與布朗大學國際合作項目的律師 Peter C. Lauro 在內，當天還至少有二名西人出席。

對北京感興趣的人很多，周衛民講談結束後，與會者紛紛圍著他提問。菊子攝

2010醫療器械和診斷技術研討會

世界日报記者李靜雯 麻州渥森市報導

美中生物醫藥協會 (CABA)、紐英倫中華資訊網路協會 (NECINA) 和北美中華醫學會 (ACMA) 日前在渥森市 IBM 創新中心共同舉辦「2010 醫療器械和診斷技術研討會」，探討醫療器械和診斷技術的技術革新、市場戰略、知識產權以及中美兩國在此領域的創業現況，超過 100 名業界人士參加。

CABA 會長戴朝陽、副會長車慶林表示，這是該會第二年舉辦關於醫療器械與診斷技術方面的研會，此領域與製藥業相比，進入門檻低，且大中國市場對醫療器械的需求大。

為共享資源，促進大波士頓地區醫療器械、高科技業與醫學界專業人士交流，研討會首次由三個專業團體聯合舉辦。

NECINA 與會代表鄭茹及朱曉峰表示，NECINA 設有生物資訊科技業小組，對醫療器械的問題相當關注。ACMA 的朱正侖則表示，該會多由醫師組成，是醫療器械的實際使用者，能夠提出許多臨床的意見。

該研討會主要組織者張偉表示，本次研討會主要從商業與科技角度，分析醫療器械發展現況與前景。

主講者包括創業家、科學家、醫生、公司主管、學界專家及市場分析專家等。

Milstein Zhang & Wu 律師樓合夥人張引、波士頓生物醫藥諮詢公司顧問史記，以及 Vascular Science 公司總裁朱思 (Michael Drues) 等認為，中國目前的市場空間很大，與製藥業相比，醫療器械業研發金額較小，同時研發周期較短，極具優勢。

Neurometrix 公司副總裁孔軒則介紹醫療診斷器械的研發與市場策略。哈佛大學 Whitesides laboratory 研究員鄭兆珉則介紹最新的紙張診斷科技。AST Products, Inc. 研發部門主管李威聯介紹人工水晶體 (intraocular lens) 的最新發展。

麻州總醫院吳世新醫師從腎臟醫學的角度，談醫療器械的研發與創新。

最後舉行小組討論，布里根婦女醫院腸胃部門醫師朱正侖、Boston Scientific 研發部門主任李建民、吳世新，以及史記等參與討論，並回答與會者提問。

CABA等三协会合办2010 医疗器材研讨会

星岛日报记者菊子华森市报道

美中生物医药协会 (CABA) 和纽英伦中华资讯网路协会 (NECINA) 和北美中华医学会 (ACMA) 携手合作，日前在华森市 IBM 创新中心举办「2010 医疗器械和诊断技术研讨会」，从市场行销、科技创新的角度做探讨，协助相关人士从这约有三千亿美元市场的领域，发掘机会。

根据医药业界报导，医疗器材业 2009 年的全球销售额已超过 2200 亿美元，其中美国占 41%。

波士顿生物医药谘询公司 (Boston Biomedical Consultants) 资深市场研究分析师史记，当天则指出，中国政府为因应人口老化，推动全民健保等需要，已估计国内的医疗器材业市场规模，到 2020 年时将达十兆元人民币。

美中生物医药协会 (CABA) 会长戴朝阳、副会长车庆林，以及会议筹办者张伟表示，该会因此今年再接再励的举办医疗器械与诊断技术研讨会，为会内有心在这一领域发展人士，制造机会。

纽英仑中华资讯网路协会 (NECINA) 总经理郑茹则指出，医疗器材的设计、应用，经常要配合使用创新资讯技术，该会新近成立，由朱晓峰博士任召集人的生物医疗科技兴趣小组，很高兴有机会参与合作举办这场研讨会，促进相关业界从业人员的交流。

北美中华医学会 (ACMA) 会长朱正伦表示，该会的参与，主要从医师是使用者的角度，来提供回馈意见。

这场「2010 医疗器械和诊断技术研讨会」共分市场行销、科技创新，以及座谈等三个环节。

市场行销部份，有辅导者资金合伙人 (Mentor Capital Partners)Erik Molander 讲医疗器材业的投资策略，Neurometrix 公司副总裁孔轩谈研发及诊断业务，Milstein Zhang & Wu 律师楼合伙人张引谈医疗器材业 (MDDI) 的专利权策略，波士顿科学公司全球科技项目主任 Chris McFadden 讲谈「供应链自动化策略」。科技创新部份，有哈佛大学白边 (Whitesides) 研究组研究员郑兆则介绍最新的纸张诊断科技，Vascular Science 公司总裁卓斯 (Michael Drues) 谈临床优点、法规问题及生产等的挑战，AST Products, Inc. 研发部门主管李威联介绍人工水晶体 (intraocular lens) 的最新发展，麻州总医院医师吴世新从肾脏医师的角度，谈医疗器械的研发与创新。

座谈部份有布里根妇女医院肠胃部医师朱正仑、波士顿科学公司研究发展主任李建民，以及卓斯、吴世新，史记等人回答现场提问。

李建民在会中坦承，虽然他是中国人，但来美已廿多年，回到中国时，感觉自己对今日中国，以及今日中国人的哲学理念、态度，实在了解不多，有心回中国发展者，恐怕还是得花些时间做功课才行。

湖南省波城推廣國際生醫交流

星岛日报记者 周菊子 波士顿报道

湖南省政府和美中生物醫藥協會合作，于十一月廿日下午在劍橋市凱悅酒店舉行的「湖南省生物醫藥產業國際交流推介會」，以及 2010 年美中生物醫藥協會「科技、投資、創業研討會」，既有中國商務部副部長傅自應致詞，湖南省副省長甘霖主講的隆重，還舉行了全美湖南工商會成立的授牌儀式。

本身是湖南人的中國商務部副部長傅自應和湖南省副省長甘霖，目前都是哈佛大學甘迺迪政府學院的新世界項目訪問學者，這天特地出席，為湖南造勢。

▲美中生物醫藥協會會長戴朝陽（後左五）、前會長萬昭奎（後右五）、董事會主席王義漢（後右四），美中知識產權律師協會創會會長張引（前右一起）等主辦者，和演講嘉賓姜灿文、甘霖、Imran Nasrullah、Angus G. McQuilken、Tim Clackson、蔡凌希、李維廉等人合影。
菊子攝

湖南省商務廳廳長劉捷率領的十八人生物醫藥代表團，到波士頓，參訪健贊 (Genzyme) 等生醫公司，也在推介會上介紹湖南的長沙國家生物產業基地、長沙高新技術產業開發區，以及株洲市。

傅自應廿日在會中表示，湖南省此時選擇到大波士頓招商，既選對了時間，也選對了地點，因為明年開始的中國第十二個五年計劃，重點之一就是要發展人類健康產業，以因應再過十年，中國社會人口邁向老年化的現實，而麻州正是生命科學重鎮，共有不下 480 多家生物醫藥公司，其中 227 家有自己的核心科技，截至今年八月底，已研發出不下 895 種新藥，等著美國聯邦藥物管理局 (FDA) 批准。

▲美中生物醫藥協會成員應湖南衛視要求，預錄向湖南鄉親拜年的鏡頭。
菊子攝

◀美中生物醫藥協會會長戴朝陽（左一）與哈佛燕京圖書館館長鄭炯文（右二）、該館馬小鶴（右一）、楊麗暄（左二）一起歡迎中國商務部副部長傅自應到會。
菊子攝

湖南省副省長甘霖（右）和哈佛燕京圖書館館長鄭炯文（左）在贈書儀式中還有頒表揚狀等儀式。
菊子攝

湖南農業大學園藝系畢業，2003 年起就擔任湖南省副省長的甘霖，這天以「互動、合作及生醫產業雙贏局面 (Interaction, Collaboration and a Win-win for Bio-medicine)」的講題，介紹湖南省概況，鼓勵中美合作。

甘霖指出，湖南是中國中部六省之一，也是發展最快的一省，佔地 21 萬平方公里，人口六千九百萬，自然資源豐富，既有漁米之鄉的美譽，也是有色金屬之鄉，非金屬礦產之鄉，旅遊勝地，還是長沙—株洲—湘潭市集團資源及環境保護實驗區。過去連續四年的經濟成長率都在 12% 以上。

她指出，湖南已和世界上的二百多個國家及地區建有經貿關係，出口 3000 多種產品，也有包括 50 家名列世界 500 強的逾 3000 家外國公司，已進湖南投資。在中國的境外直接投資總額受全球經濟不景影響，下降了 2.56% 之際，湖南卻不減反增 14.8%，達到 46 億美元。

湖南的具競爭力企業，也加快了「走出去」的速度，去年投資到海外的數額高達美金 10.2 億元，在中國的 31 省及自治區中排名第一。目前有 27 家湖南企業已獲湖南商務廳批准，在美國投資。其中的三一 (Sany) 重工業在喬治亞州投資建廠，第一期斥資七千萬美元。

生醫產業是湖南省要重點發展的七大產業之一，2006 年以來的年均增長高達 35.8%，2009 年產值高達 50 億美元，在中國排名第13。湖南也有兩個國家級的生醫產業基地，國家生物產業基地，國家傳統中藥臨床研究基地。湖南境內基本上已完整的建立了醫藥產業體系，共有 25 家醫藥生產企業，年產值達人民幣十億元。從 2006 年以來，湖南的生醫企業也獲得了 300 項專利，320 項國家級新藥或新醫療器材登記證。境內有 15530 家零售藥店的湖南，有至少五家醫藥連鎖企業年銷售額達四億元，名列中國的五十大。

估計到 2020 年時，中國的生醫產值將達到 6000 億美元，超過日本、歐洲，成為世界上第二大的醫藥市場。其中湖南的生醫產業年銷售收入，估計到 2015 年時將超過 180 億美元，擠身中國的前十大之一。

在湖南可創造最佳雙贏環境上，甘霖指出，湖南的地理位置四通八達，交通便利，境內每 100 平方公里有快速公路 1.46 平方公里，比美國的 0.95 還高。時速可達每小時 350 公里的武漢、廣州高速鐵路通車後，從長沙到廣州，只要兩小時。在長沙到昆明的另一條高速鐵路通車後，從長沙到上海，只要三小時。這將大為改變湖南與境外、海外的合作條件。

在「湖南省生物醫藥產業國際交流推介會」環節中，長沙國家生物產業基地管理委員會助理主任暨湖南省實驗動物中心主任陳志高，介紹了 2010 年獲批為國家新藥創制孵化基地的長沙國家生物產業基地概況，指出該基地已成立了醫藥企業營運聯合體，湖南醫藥集團，並已組成第一期有 2.5 億元的納新產業基金，要打造千億元產業園區，迄今招攬的人才中已有段燕文、鄭群逸兩人入選國家千人計劃。長沙高新技術產業開發區副主任鄧自力，湖南省株洲市常物副市長王志剛等人，當天也分別介紹了各自服務機構的概況。

在李勁波、美中生物醫藥協會會長戴朝陽主持的 2010 年美中生物醫藥協會「科技、投資、創業研討會」環節中，有 Angiogensis 基金會創辦人李維麟，默克 (Merke) 公司劍橋市分部負責人 John Piwinski，Spring Bank 執行長 Douglas Jensen，麻州生命科學中心副總裁 Angus G. McQuilken，麻州生物會 (MassBio) 商業發展長 Imran Nasrullah, Ariad 製藥公司董事長 Tim Clackson，健贊 (Genzyme) 全球副總裁姜火山文，Bioduro 業務拓展副總監蔡凌希等人講談。

會議中還安排了一場贈書儀式，由湖南省副省長甘霖代表，贈送了一套古籍給哈佛燕京圖書館，由館長鄭炯文接受。整場會議，都有湖南衛視現場拍攝。會後拍了美中生物醫藥協會與全美湖南工商會向湖南人民拜年的畫面。

天津港保稅區空港經濟區代表團首次訪波士頓

星岛日报记者 周菊子 波士顿报道

透過美中生物醫藥協會協助，天津港保稅區空港經濟區駐美國辦事處，于七月十日首次來訪波士頓，向大約六十名出席者說明，座落在該區內的中國科學院工業生物技術研究所，此刻正招攬人才，呼籲有意回中國發展的生醫界專業人士，選擇落腳天津。

在中國，天津是地位和北京、上海、深圳，以及近十年才升格的重慶等，並駕齊驅的直轄市。天津港保稅區空港經濟區駐美國辦事處主任馮大正表示，該區地位特殊，已率先實現地方立法，形成了海空兩港一體化運作的物流體系，發展條件比中國內的許多其他城市都要好。

馮大正當天除了介紹天津空港經濟區內的中國科學院工業生物技術研究所，區內概況，投資政策與發展趨勢，具有規模及水準的孵化平台建設之外，也在會後透露，天津很早就來到美國設辦事處，他和張鵬、李萌等三人已是第三批天津駐美的工作人員。由於天津以往較注重金屬、礦產、汽車等重工業，又講究經濟效益，當年選擇了南卡羅萊納州設辦公室。現在為配合生物醫藥產業是全中國未來發展重點的趨勢，天津才和美中生物醫藥協會合作，來大波士頓參訪，拜會生物醫藥公司，同時舉辦「2010 年天津招商推廣會」，為天津招納人才，吸引商家。

美中生物醫藥協會執委王志剛（左一）、天津港保稅區空港經濟區駐美國辦事處主任馮大正、王義漢、李萌、車慶林、張鵬等人當天在會場留到最後，繼續討論兩機構的未來合作。
菊子攝

馮大正等人在會中介紹了濱海新區、1991 年 5 月 12 日經國物院批准成立，具有國際貿易、現代物流、臨港加工和商品展銷等四大功能的天津港保稅區 (TJFTZ) 空港經濟區 (TAEA) 等的開發情況，重點產業，區域優勢，以及該區在

大力吸引生物醫藥、航空航天、新材料新技術等產業進行投資的海關、稅收、外匯等優惠政策。

馮正大也指出，生物醫藥業是天津的支柱，也是成長最快的高科技工業之一，市內共有 52 所大學院校，230 個技術學院，具備研發所需的基本人才條件。2009 年三月，中科院和天津合作，成立了「中科院、天津生物科技工業院 (Tianjin Institute of Industrial Biotechnology, Chinese Academy of Sciences (TIB, CAS))」。要重點發展工業化的生物科技系統，促進天津及渤海區的可持續發展，透過創新及孵化中心，來帶動工業化生物科技的整合及轉型標準，也使天津在生物醫藥業的發展上更具競爭力。

包括中華資訊網路協會會長陳君瑤、副會長陸德禮，北美中華醫學會前會長朱正倫等人都到會支持。

查詢天津港保稅區空港經濟區詳情可上網 www.tjftz.gov.cn，或 www.tib.cas.cn。

五華人專業團體Hopkinton郊遊再掀交流熱潮

星岛日报记者 周菊子 波士顿报道

新英格蘭地區的五個華人專業團體，八月十四日下午匯聚了三百五十多人，到麻州霍普京頓 (Hopkinton) 州立公園，享用中式自助餐，打排球，拔河，划船，或在樹蔭下納涼，閒聊，又一年的開心交流。

今年合作籌辦這聯合郊遊的團體，仍為北美中華醫學會 (ACMA)、美中生物醫藥協會 (CABA)、中美知識產權法律協會 (CAIPLA)、留美華人企業家聯合會 (OCEAN)。

已於之前一週辦過郊遊活動的紐英崙中華資訊網路協會 (NECINA)，由副會長陸德禮、總經理鄭茹等人代表出席，以示支持。今年負責統籌這聯合郊遊活動的黃玲、鄺平平表示，有了第一年的經驗後，今年的一應細節，包括安排專人到紅線、綠線地鐵站接載不開車的人等，都辦得更順暢。金門超市總經理胡運炤也特地請大廚提早準備飯菜，不到中午十二點，就已送到現場，讓出席眾人能在輕鬆心情下，井然有序的分成三組，及時取用午餐，再三三倆倆各自聚談，會場氣氛很悠哉。

各協會主要幹部，包括仍為北美中華醫學會會長朱正倫、美中生物醫藥協會董事會主席王義漢、前會長韓軍、副會長車慶林、常務理事金聖芳，中美知識產權法律協會創會會長張引、現任會長顧鴻生、留美華人企業家聯合會董事會主席胡運炤，以及清華大學校友會會長張偉，創辦 Vaso 科技公司的吳天根，中央黨校哲學與戰略教授段培君等人，當天都在郊遊活動中各自交流。

五專業團體的主要幹部在會中合影，包括楊欽釗（後排左起）、韓軍、張引、楊志勇（後左五起）、王義漢、張偉、車慶林、胡運炤、朱正倫、朱曉峰，林世文（後右三），以及鄭茹（前右三起）、陸德禮、黃玲、金聖芳（前左一）等人。
菊子攝

他們今年採取的統一報名做法，也使活動結束後的總結帳目，辦得更快速。黃玲表示，唯一出人意料之外的是，原本有將近五百人報名，但受麻州放銷售稅假影響，結果只有三、四百人出席。

十四日當天攜家帶眷出席這郊遊活動的，有不少人已是第二年參加，場地、人頭都熟，交流得也更熱絡。有項目，要辦活動的，更是樂得藉此機會做宣傳。

留美華人企業家聯合會教育部主任吳凱彬就印了許多傳單，宣傳該會將於八月廿一日（週六）晚六點半到八點半，在麻省理工學院 E-25 大樓 117 室，舉辦「麻州的各種企業形式分析」講座，邀請具中美兩國法律學位的田勝昔律師，講談商法、基本稅法。他還預告該會的第十一期商管培訓班將於十月底開課，增加了管理及人際溝通的課程內容。

新近成立了波士頓林肯國際合作公司的張偉儀、林世文，還和美中生物醫藥協會、麻省理工學院中國學生學者聯合會合作，將於八月廿八日（週六）早上九點至十二點，在麻省理工學院 E-51 大樓，315 室舉辦講座，邀武漢市食品藥品監督管理局講談如何提升中國中部生物產業。

由華人 Thomas Chi 所創辦 Luknova 公司的市場行銷主任 Ronald E Vincent 也和張伯科交流，協助本地生物醫藥領域華人，瞭解中國國家藥監局 (SFDA) 管理辦法可有那些做法等。

黃玲會後特別指出，今年的郊遊活動能順利舉辦的大功臣之一是 OCEAN 主席胡運炤，不但捐助自助餐，還贊助了至少一百元給出席的小朋友們買冰淇淋。熱戰排球的兩隊成員，也留到最後，幫忙把場地清理得不見一屑，才離開。

無錫濱湖區訪波招才 推530計劃

星岛日报记者 周菊子 波士顿报道

中國江蘇無錫市濱湖區廿一日在波士頓華埠凱悅酒店舉辦無錫「530 千人計畫」推介會，說明無錫濱湖現正積極建設國家傳感信息中心，重點發展物聯網、生物醫藥，區內太湖新城、蠡湖街道，蠡園經濟開發區各有優點，將和鄰近上海等要城形成半小時生活圈。

中國江蘇無錫市濱湖區代表團一行六人，包括副區長吳建昌、太湖城管委會副主任孫海東、蠡湖街道辦事處副主任劉卿、蠡園經濟開發區項目招商局副局長馮宇宏、濱湖區科學技術局局長吳雲亮，以及經濟和信息局副局長鄒心橋，當天在凱悅酒店一樓舉行企業家培訓班，在二樓辦推介會。陪同代表到會的有無錫正華生物醫藥技術公司執行長陳以旺，無錫迦俐申生物醫藥公司姚飛。

中國江蘇無錫市濱湖區蠡湖街道辦事處副主任劉卿（前左起）、榮光輝、姚飛、濱湖副區長吳建昌、CABA 王義漢、網協鄭茹（前右四）、蠡園經濟開發區項目招商局副局長馮宇宏（前右一）、孫東海（後右一）、陳以旺（後左一）、安寧（後左二）等人會後合影。
菊子攝

吳建昌在會中表示，無錫市是中國最具幸福感城市之一，濱湖區則是無錫市內名列前茅的市轄區，近年來依循建設無錫現代化的要求，積極推動物聯網、軟件與服務外包、IC 設計與工業設計、生物醫藥、影視文化、網絡經濟、通訊技術、航空電子等八大新興產業，並配合無錫（國家）工業設計園、太湖新城科教產業園、無錫國家生命科學園、無錫（濱湖）國家傳感信息中心、蠡湖科技創業園等五大品牌園區謀求發展。他也說明，無錫的雲計算中心已被國家發改委選為全中國的五大中心之一。

吳建昌指出，自 530 計劃從 2006 年實施以來，濱湖區已有 427 家 530 計劃企業落戶，為國家「千人計劃」引進十名人才，還建設了 250 萬平方米的載體，已建成科技企業孵化器六家，培育了高新技術企業 56 家，建成了國家級集成電路設計中心、軟件測試中心、超算中心、雲計算中心等公共服務平台。該區有成立了 530 工作辦公室，530 項目促進中心，制定出台了總額達 15 億元的新興產業發展基金，創辦了註冊資金一億元的無錫濱湖科技創業投資公司，引進了 15 家以上的創投基金公司，在 2010 年內，全區已有近百家 530 企業實現了產業化，納稅銷售總額超過 1.5 億元人民幣，其中年銷售額超過一千萬元人民幣的 530 企業有 8 家。

吳建昌也指出，在引進海外領軍創業型人才上，無錫市的 530 計劃有著給落戶者一次性四十到一百萬元人民幣啟動資金，提供不少於一百平方米工作場所，不少於一百平方米公寓住房，對於具產業化前景的項目，還撥給不低於三百萬元人民幣的風險投資等優惠。

孫東海重點介紹太湖新城中心，指該城是無錫唯一綜合科技研發及創意的基地，既是生態城，也是旅遊與現代服務業、高科技產業、宜居城，無錫（濱湖）國家傳感信息中心就座落在太湖新城內，中科院電子所傳感氣網絡信息技術研發中心、無錫新潔能功率半導體公司、無錫神州天信物聯在線信息科技公司等都已落戶該中心。他指出，除 530 計劃外，無錫還推出過「123 計劃」，要聚集國際服務外包和軟件出口企業 100 家，每家企業從業人員超過 2000 人，每年出口超過 3000 萬元。

劉卿主要介紹無錫蠡湖科技創業園，早於 1999 年經市政府批准設立，已於 2008 年建成蠡湖科技大廈，引進 530 企業 35 家，2009 也被批准為省級留學生創業園、省重點培育小企業創業基地。該園區和聯合國工發組織，科技部火炬計劃中心等多次洽談，計劃三到五年內，把該園區建澈成新能源、新材料、和清潔技術的新興產業聚集區。

馮宇宏主要介紹無錫（國家）工業設計園。她指出該園是全中國唯一的國家工業設計知識產權中心，建有綠色通道，可在協助企業快速取得知識產權。目前正在建設創意園。

協助江蘇無錫市濱湖區舉辦這 530 計劃推介會的本地機構，包括美中生物醫藥協會 (CABA)、紐英崙中華資訊網路協會 (NECINA)。出席者包括負責協調這一活動的網協中國興趣小組負責人安寧，CABA 董事會主席王義漢、NECINA 總經理鄭茹，128 華人科技企業家協會理事榮光輝等人。

CABA Leadership Team Update

2011-2012 CABA Executive Committee and Key Team

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Sr. Research Investigator, Eisai Research Institute,
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Vice Presidents

Zhiyong Yang, Ph.D.
Principal Scientist, Pfizer BioTherapeutics Research,
Cambridge, MA

Qinglin Che, Ph.D.
Research Scientist, Synta Pharmaceuticals Corp.,
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Sue Ma, M. D.
Scientist II, Novartis Institute of BioMedical Research,
Cambridge, MA

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Scientist II, Arsenal Medical Inc.
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Jia Huang, Ph.D.
Scientist, Allergan Inc.,
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Jinbo Lee, Ph.D.
President, Sage Partner International Inc.,
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Shengfang Jin, Ph.D.
Director/Cell Biology, Agios Pharmaceuticals, Inc.,
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Susan Qu, Ph.D., MBA
Principal Project Manager Genzyme Corporation, a division of Sanofi,
Framingham, MA

Ji Shi
Senior Market Research Analyst, Boston Biomedical Consultants,
Waltham, MA

Shallwei Sun
General Manager, Callisyn Biomedical, Inc,
North Andover, MA

Ze Tian, Ph.D.
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Deputy General Manager, Kanghong Biotechnology Co. Ltd.,
Chengdu, China

Yueming Wang, MBA
Deputy General Manager, Tide Pharmaceutical Co. Ltd.,
Beijing, China

Zhigang Wang, Ph.D.
Principal Scientist, Avila Therapeutics,Inc. Bedford, MA

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President and CEO of Conform Pharmaceuticals Inc,
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Director, Scilligence,
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Co-founder and Co-Managing Principal, Milstein Zhang & Wu LLC,
Newton, MA

Wei Zhang, Ph.D.
Staff Scientist, Siemens Healthcare Diagnostics,
Norwood, MA

Weiyi(Wendy) Zhang, Ph.D.
President, Boston Lincoln International,
Lincoln, MA

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Principal Scientist, Avila Therapeutics, Inc.,
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CEO, SOTA International LLC.,
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Associate Director, Process & Analytical Technologies, Agenus, Inc.,
Lexington, MA

Lixin Shen, Ph.D.
President and CEO, Wuxi Howfond Biopharma Co., Ltd.,
Wuxi, Jiangsu, China

Zhao-Kui Wan, Ph.D.
CABA President (2009-2010)
Sr. Principal Scientist, Pfizer Inc.,
Cambridge, MA

Erxi Wu, Ph.D.
Assistant Prof., North Dakota State University,
Fargo, ND

Junjun Wu, Ph.D.
CABA President (2008-2009)
Principal Research Scientist, Pfizer Inc.,
Cambridge, MA

CABA Advisors

Youssef Bennani, Ph.D.
Vice President Research & Development, Vertex-Canada at Vertex Pharmaceuticals

Tim Clackson, Ph.D.
President of Research & Development and Chief Scientific Officer, Ariad Pharmaceuticals Inc.,
Cambridge, MA

Yuan-Hua Ding, Ph.D.
Senior Director & Head of External R&D Innovation - Asia, Pfizer

Pierre Dodion, M.D., MBA
Sr. VP/Corporate development, Ariad Pharmaceuticals Inc.,
Cambridge, MA

Chen Li, Ph.D.
Chief Executive Officer, Hua Medicine, Inc.,
Shanghai, China.

Shi Li, Ph.D.
CEO, Zerun Biotechnology,
Shanghai, China

Yuanli Liu, Ph.D.
Director of China Initiative, Sr. Lecturer on International Health, Harvard School of Public Health

Dawei Ma, Ph.D.
Professor, Shanghai Institute of Organic Chemistry,
Shanghai, China

Tarek Mansour, Ph.D.
EVP of Research & Development, Xenon Pharmaceuticals Inc.,
Vancouver, Canada

Tse Ping
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Beijing, China

John Piwinski, Ph.D.
Principal, JJPiwinski Pharma Consulting, LLC,
New York, NY

Steve Projan, Ph.D.
Sr. V.P. R&D, Innovative Medicines Head of Infectious Diseases & Vaccines, MedImmune,
Gaithersburg, MD

Tomi Sawyer, Ph.D.
Chief Scientific Officer and Senior Vice-President Discovery & Innovative Technologies, Aileron Therapeutics,
Cambridge, MA

Liming Shao, Ph.D.
Senior Director/Medicinal Chemistry, Sunovion Inc.,
Marlborough, MA

Suvit Thaisrivongs, Ph.D.
Vice President, Pfizer, Inc.,
Cambridge, MA

Roger Tung, Ph.D.
CEO and President, Concert Pharmaceuticals,
Lexington, MA

Yibin Xiang, Ph.D.
Senior Director/Medicinal Chemistry, Genzyme Corporation, a division of Sanofi,
Cambridge, MA

Gangfeng Xu, Ph.D.
Divisional Vice President, Corporate Licensing & Acquisitions at Abbott Laboratories

Steve Yang, Ph.D.
Head of R&D, Asia & Emerging Markets, AstraZeneca

Howard Yuwen, Ph.D.
Sr. Director, Regulatory Affairs, Shire Shire Human Genetics Therapies,
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WSGR

Simcere Pharmaceutical Group: Living up to the Patient Expectations

Simcere Pharmaceutical Group was incorporated on March 28, 1995. In the sixteen years since its inception and with over 4,000 employees nationwide, Simcere has become a fully integrated pharmaceutical enterprise with a leading R&D organization, six GMP manufacturing facilities and strong sales and marketing capabilities.

On April 20, 2007, Simcere successfully debuted on the NYSE (ticker: SCR) as the first NYSE-listed biopharmaceutical company from mainland China.

On July 21, 2011, Simcere made yet another pioneering strategic move by signing a framework agreement with Merck & Co. to form a joint venture in China to develop, manufacture, and commercialize branded generic drugs. By combining the strength of a multinational pharmaceutical company and a local leading player, this first-of-its-kind partnership aims to broaden market access to quality medicine for Chinese patients.

Simcere's product portfolio includes more than 45 differentiated products covering the therapeutic areas of oncology, cerebrovascular diseases, cardiovascular diseases, infection and inflammation. Among its in-line portfolio, Endostar is a novel recombinant human endostatin approved for treatment of lung cancer. Bicun (Edaravone Injection)was the first anti-stroke drug launched in China and is widely used as s standard treatment in after-stroke management. It is recognized as a 'Well-known Chinese Trademark'.. Moreover, Yingtaiqing and Zailin are also recognized as 'Well-known Chinese Trademarks'. In 2009, Yingtaiqing became a promotion partner of the NBA in the China market. Furthermore, Simcere's generic diosmectite marketed under the brand name "Biqi" for the treatment of diahrrea has passed EU-GMP inspection for both its formulation and API manufacturing in 2011 and is authorized to market and sell in the EU countries.

Simcere's Research and Development Institute was established in 2004. Its capabilities include early stage discovery, medicinal chemistry, antibody discovery, preclinical development, CMC and process development, clinical operations and regulatory affairs. Since 2007, Simcere R&D has filed for 60 patent applications, including 6 PCT applications. In addition, Simcere R&D has obtained 18 NDA approvals and 26 IND approvals. In 2011, Simcere revealed its expanded R&D Center at its headquarters in Nanjing, and the new facility has over twenty-six thousand square meters and houses the most advanced pharmaceutical research and development technologies.

Simcere's R&D strategy is focused on developing innovative and first-to-market medicine for diseases with high mortality and morbidity. The key objective of Simcere's research and development efforts is to deliver medicine to meet the high unmet medical needs in the therapeutic areas of oncology, neuroscience, cardiovascular and metabolic disease, infectious disease and inflammation. There are currently over twenty programs under development in Simcere's R&D pipeline, five of which entered Class I IND filing last year and are expected to enter the clinic later this year. In August, 2011, Simcere received the approval from the SFDA to manufacture and market Iremod (iguratimod tablet) for the treatment of rheumatoid arthritis. It is a first-to-market drug independently developed by Simcere, and clinical studies demonstrate that Iremod can significantly alleviate symptoms caused by active rheumatoid arthritis.

Externalization is a critical part of Simcere's R&D strategy. In 2009, Simcere entered a licensing and co-development partnership with Epitomics, a biotech company based in San Francisco, U.S. to develop a novel rabbit-based monoclonal antibodies.. In the same year, Simcere entered an agreement with OSI, leading biotech company in the U.S., to develop a novel chemical compound for oncology indications. Last year, Simcere further expanded its R&D collaboration network by entering into a strategic partnership with Bristol-Myers Squibb Co. Ltd. (BMS) to develop a novel oncology compound. Under this partnership, Simcere will be granted the exclusive rights in China to develop and commercialize a compound developed by BMS.

Simcere's mission is to lead the development of innovative medicine in China, to provide effective treatment to serious disease, and to better the lives of the Chinese people. We are committed to serve our patients, physicians, and communities with pride, compliance, and the utmost integrity.

CITY STORY

Biolake 光谷生物城

武汉国家生物产业基地--光谷生物城

武汉国家生物产业基地(即光谷生物城)位于武汉东湖国家自主创新示范区 · 武汉中国光谷，是中国光谷以“千亿产业”思路建设的第二个国家级产业基地。

光谷生物城总规划面积 28 平方公里。建设生物创新园、生物医药园、生物农业园、医疗器械园、生物能源园、中新（武汉）生物科技园，打造集研发、孵化、生产、物流、行政、居住为一体的生物产业新城。

2008 年 11 月，光谷生物城开工建设，基础设施和功能配套快速推进。建立了生物产业技术支撑、技术服务、企业孵化、信息资源共享、投融资、人才引进等“六大服务平台”，为生物企业的集聚发展营造了良好的综合环境。

2011 年 11 月，光谷生物城开工建设三周年，六大园区开工建设总面积 300 万平方米，协议入驻企业 300 余家，100 余家企业入驻或投入运营，其中世界 500 强企业 3 家，上市企业 10 家，引进“3551”生物人才团队和院士项目 125 个，7 个国家级平台获批建设，与 30 多个国家和地区签署合作协议，生物产业实现年总收入 300 亿元。

预计到 2020 年，光谷生物城将集聚各类生物企业超过 1000 家，实现生物产业总收入过 2000 亿元，成为“特色鲜明、实力雄厚、国内领先、国际知名”的生物产业基地。

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P. O. Box 600241

Newtonville, MA 02460 USA

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