

## **U.S.-China Economic and Security Review Commission**

### **Hearing On: “China’s Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products”**

April 3, 2014

“Market Access for U.S. Medical Goods and Services in China”

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For pharmaceutical, medical device and diagnostic life science manufacturers across the United States, the China market has become increasingly important over the last decade. China – and emerging markets in general – offers the industry a largely untapped and growing market where basic healthcare needs have long gone unaddressed, and where a growing middle class exhibits a strong preference for spending on healthcare goods and services. McKinsey’s China healthcare practice estimates that the country’s healthcare spending would grow from \$357 billion in 2011 to \$1 trillion by 2020.<sup>1</sup>

For pharmaceutical companies in particular, the China market has become a significant driver of growth: in 2010, the domestic Chinese over-the-counter (OTC) and branded generic market was approximately \$23 billion, by 2020 it is projected to have reached over \$369 billion in size. If this holds, China will become the world’s second largest pharmaceutical market, following only the U.S. Before China represented this sort of growth opportunity, many life science companies had successfully leveraged China as part of their supply chain. Today, most have come to see the potential China market as more than an alternative, lower cost segment of their precursor supply chain. Now, many American life science companies see China as an offset to many of the revenue and profitability challenges they face in their developed domestic markets.

The specific challenges U.S. life science companies face today within their domestic market include price pressures related to an aging society with chronic long-term diseases and the need to save money, which has driven reimbursement rates down on many goods and services; a maturing patent pipeline with an inadequate number of obvious “blockbuster” drugs in the works<sup>2</sup>; cracking the human genome has thus far not yielded the sort of commercial opportunities many companies anticipated.

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<sup>1</sup> Le Deu, Franck, Rajesh Parekh, Fangning Zhang et. al, “Healthcare in China: Entering Uncharted Waters,” McKinsey and Company, July 2012, page 2.

<sup>2</sup> Within the pharmaceutical industry, a blockbuster drug is commonly understood to be one that creates over \$1 billion in annual sales.

Combined, these pressures have made success for the life science industry in emerging economies in general, and China especially, more important than ever.

Reflecting these realities, U.S. life science companies have made China a central part of their growth plans. Early on, the life science industry adopted market access strategies that reflected best practices from other un-related sectors; namely, bringing more mature products and therapies the companies could afford to lose to China if IP drift occurred. In general, this approach worked well for much of the last twenty years, until recently, when China's expectations from multinational life science companies became more sophisticated.

Since 2008, when the New Drug Creation and Development program was announced, China's appetite for western therapies has dovetailed with an explicit policy mandate by the central government that the country develop a domestic life science sector. The 12<sup>th</sup> Five Year Plan is clear in its goals: to ensure life sciences account for at least four percent (4%) of China's GDP.<sup>3</sup> To see that this objective is met, China has allocated government capital into the life science sector, created twenty new "incubator bases," formed multiple alliances between government, industry and academia, at the same time it has pushed forward on forcing its domestic industry to adopt good practice (GxP) standards, a step which provides greater confidence by foreign companies in the capability and integrity of development, trialing and manufacturing from a Chinese partner. Between 2008-2010, the Chinese government invested \$2.7 billion into pharmaceutical R&D, followed up with planned spending of an additional \$6 billion by 2015.<sup>4</sup> China has twin objectives driving these policies: to ensure the country has a viable domestic manufacturing capacity to produce basic medicines and to create a new export industry that represents higher technology products.

As a result of China's goals, American companies have found they now must begin to allocate funding towards R&D directed specifically at bench science, product development and clinical trials completed in China. Merck's late 2011 announcement that it would be spending \$1.5 billion to build a domestic Chinese R&D capacity reflects the new reality of doing business in China. Today, China is not only a potential market for American life science companies to sell into, it is also where they will increasingly be conducting R&D. The pressure to do more R&D in China has potential upside to American life science companies: not only does China have a pool of scientific talent and a policy infrastructure in place to incentivize research activities, there is also a good argument to be made for conducting development and trials in China for unique morbidities within the Chinese population.

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<sup>3</sup> Chee Hew, "Prescription for healthier growth: Shaping China's life sciences market," page 9.

<sup>4</sup> Qi, Jingzong, Qingli Wang, Zhenhang Yu, Xin Chen and Fengshan Wang, "Innovative drug R&D in China," *Nature Reviews: Drug Discovery*, Volume 10, May 2011, page 333.

American companies understand that the Chinese government's emphasis to see a domestic life science industry take root further complicates market access issues. Now, alongside traditional commercial concerns that must be managed, U.S. pharmaceutical companies in particular are faced with the increasingly clear expectation they engage in technology transfer as part of their ability to sell into the Chinese market, a market dominated by the Chinese government as the provider of public hospitals and the purchaser of pharmaceuticals, medical devices, and diagnostic equipment. On this point, it is necessary to speak to the delivery of healthcare in China because absent this explanation, it can be difficult to understand why the Chinese government's objectives could run counter to those of American life science companies.

Like many emerging economies, China's healthcare system is paid for primarily via out of pocket expenditures on the part of the consumer. These out of pocket payments take two forms: the ubiquitous "red envelope" payments of cash to doctors in exchange for preferential care, and cash payments for prescriptions and procedures – many of which are medically unnecessary, but required for the hospital to fund itself. Even after two rounds of additional healthcare-specific stimulus spending by the Chinese government in 2009 and 2011, the country's public hospitals remain badly under-funded. This historic reality has created a toxic mix of financial incentives where hospital administrators scrambling for revenue, coupled to under-paid doctors hungry for better compensation, prescribe unnecessary medicines and procedures simply to fund the hospital's ongoing operation and achieve incentive compensation by the doctors related to sale of prescriptions and procedures. The Chinese consumer has born the brunt of this inefficient and financially starved system, reflected in high out of pocket payments for healthcare (estimates are that over the last twenty years, out of pocket expenditures for healthcare in China have been in excess of 50%).<sup>5</sup> In the eyes of many Chinese, the country's healthcare system – and the government's inability to fix it – remains one of their three primary sources of discontent (the other two being corruption and pollution).

Always concerned over social stability, the Chinese government has been working to make the existing healthcare system more efficient. Thus far, these endeavors have emphasized an expansion of the government-provided healthcare insurance and driving prices down. The latter has been achieved in two ways. First is the formalization and expansion of the Essential Drug List (EDL). Second is through application of the country's Anti-Monopoly Law (AML) specifically, and more generally, the expansion of anti-bribery campaigns. As a result of these efforts, U.S. medical goods and service providers now face four fundamental challenges in China: price pressure if they wish to be included in the country's tenders for

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<sup>5</sup> Zhang, Lufa, Nan Liu, "Health Reform and Out-of-Pocket Payments: Lessons from China," *Health Policy and Planning*, Oxford Journals, February 21, 2013, <http://heapol.oxfordjournals.org/content/early/2013/02/21/heapol.czt006.full>.

pharmaceuticals and devices, growing expectations they accommodate technology transfer to their Chinese counterparts, un-even enforcement of the country's AML, and a willingness on the part of the Chinese government to divert attention away from its own failings relative to healthcare by drawing attention on non-compliant behavior (i.e. corruption) on the part of domestic and multinational companies selling into China's healthcare economy.

Central procurement via the EDL remains the most obvious form of price pressure that companies face today. The EDL is a list of some 520 drugs whose prices are capped, and the traditional 15% hospital mark-up is not allowed. China's Ministry of Health (MOH) has established standards for how much of a hospital's prescribing volume should be drugs on the EDL, simply as a means of ensuring hospitals do not look for drugs off the EDL as a way of continuing to make up their revenue short-falls. As becomes obvious quite quickly, absent additional government-sponsored reimbursement schemes for hospitals, the EDL simply accentuates an already-broken funding mechanism within China's healthcare system. There are ways around these constraints – at least for now – such as sub-headings within regional tenders for what are called “off-patent originator products” (OPO) that allow greater pricing flexibility<sup>6</sup>; however, the policy mandate that is driving the EDL forward is to make pharmaceuticals affordable to more people. This emphasis is entirely understandable from the point of view of China's government and its people; the question is whether efforts such as the EDL are going to be adequate to achieve the sorts of public health objectives around access and affordability that are required.

These questions are ones shared by the Chinese government. The EDL represents a formal and structured vehicle within which various stakeholders ranging from public health policy makers in the MOH, to those setting reimbursement policies in both the MOH and Ministry of Finance (MOF) can try to expand access while controlling cost. Yet, the Chinese government also recognizes that the EDL on its own will be inadequate, simply because the list will never be exhaustive, and companies (both domestic and international) may work to stay off the EDL as a way to maintain profits while selling to a market that is admittedly smaller than they could if they were to go on the EDL.

Because of this realization, China's policy makers recognize other approaches will be necessary to make healthcare more affordable. Given the main drivers of healthcare affordability in China are pharmaceutical inputs, the Chinese government has begun a two-pronged strategy outside of the EDL to drive prices down. The first emphasizes China's AML, largely as enforced by the National Development and Reform Commission (NDRC). The second is pursuit of corruption charges such as

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<sup>6</sup> Chen, Helen, Samuel Han, “Insider Analysis From LEK On Tackling China's EDL Challenge: Navigating The Changes And Planning For Success,” *PharmaAsia News*, May 3, 2013, page 2, <http://www.lek.com/sites/default/files/L.E.K. Tackling Chinas EDL Challenge PharmaAsia May 2013.pdf>.

those leveled against GlaxoSmithKline (GSK) during the summer of 2012. While tactically different approaches, both have been successful at lowering prices for various healthcare goods across China.

The NDRC's AML enforcement capacity includes the ability to fine companies – both domestic and foreign – that are engaged in monopolistic pricing. Most industry analysts expect 2014 to see a spate of similar AML charges from the NDRC that will impact pharmaceutical, medical device and diagnostic equipment manufacturers. Few can question the immediate efficacy of an NDRC investigation: following the NDRC's AML charges against Nestle, its prices were dropped by 11% on average. Similarly, following the NDRC's 2012 focus on four drug classes that included more than 500 different drugs, prices dropped 17%.<sup>7</sup>

Often times – but not always - AML allegations go hand in hand with China's anti-corruption drive. This has led to a certain amount of cynicism about the application of China's anti-bribery standards. The best example of this so far has been the allegations leveled against GSK in the summer of 2013. In July 2013, GSK admitted that certain members of its business in China had engaged in bribery as a means of securing prescriptions from various hospital administrators and doctors.<sup>8</sup> Much of the bribery in question took place through third party travel agents who acted as proxies to redirect money from GSK towards key referral sources within the Chinese healthcare system. Since the allegations against GSK were made public, the company has announced a round of price reductions.

There are at least three ways to understand the GSK scandal in China. First, that the crackdown on GSK is part of the growing anti-corruption program Chinese President Xi Jinping has set in motion. In August of 2013, two senior executives of state owned enterprises (SOEs) were placed under "formal investigation," including Wang Yangchuan, the vice president of China National Petroleum. This way of explaining the crisis points toward a number of anti-corruption initiatives President Xi has rolled out since taking office, of which GSK is only one, and the healthcare sector is but one of several areas receiving the benefit of an anti-corruption drive.

The second way to understand the GSK scandal is specific to healthcare reform. China is in the midst of a once-in-a-generation expansion of its healthcare system. The country is making massive investments in every facet: new hospital and primary care infrastructure is being built at a torrid pace, a national insurance plan

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<sup>7</sup> Chen, Shaoyu, John Graubert, Weishi Li et. al., "China Opens Broad Investigation Into Pharmaceutical Pricing," July 19, 2013, page 2, [http://www.cov.com/files/Publication/d4f596c8-7e4b-48e7-93d2-4d8ea7505e93/Presentation/PublicationAttachment/6e573158-f4fe-4171-973e-6153c648acaf/China\\_Opens\\_Broad\\_Investigation\\_Into\\_Pharmaceutical\\_Pricing.pdf](http://www.cov.com/files/Publication/d4f596c8-7e4b-48e7-93d2-4d8ea7505e93/Presentation/PublicationAttachment/6e573158-f4fe-4171-973e-6153c648acaf/China_Opens_Broad_Investigation_Into_Pharmaceutical_Pricing.pdf).

<sup>8</sup> "Glaxo Executive Says Changes in China to Cut Drug Prices," July 22, 2013, <http://www.bloomberg.com/news/2013-07-22/glaxo-executives-may-have-violated-laws-china-ministry-says.html>.

has been rolled out that covers almost everyone in the country, providing increasing coverage for basic pharmaceuticals, devices and diagnostic procedures. Yet most, if not all of these additional investments are being built on top of a weak foundation.

Doctors are chronically over-worked and under-paid.<sup>9</sup> Hospital administrators struggle to meet shortfalls between government reimbursement and the increasing costs associated with the levels of service and medical products they are expected to provide. Both hospital administrators and doctors have found alternative means to make up for the revenue not provided by the government. For administrators, their response has been to incentivize doctors to prescribe unnecessary pharmaceuticals, surgical procedures, and diagnostic evaluations. Doctors have supplemented their paltry incomes through the sort of bribes the GSK scandal has exposed, as well as the previously mentioned “red envelope” payments that families make directly to doctors to ensure proper and timely care. The combination of these practices has created pervasive inefficiencies within China’s healthcare system that must be dealt with if the massive additional investment the country’s central government is making is going to be used wisely and actually benefit the Chinese people. Companies such as GSK did not create this environment; rather, they have had to determine how to navigate the complex field where international compliance standards overlap with how healthcare is consumed and paid for in China. The realization that companies such as GSK did not create this situation, but are bearing unequal blame for it leads to the third, and most troubling way to understand the GSK scandal: China is broadly becoming a less hospitable place for multinational companies to operate.

Over the last several years, surveys by of American and European companies with significant investments in China have noted growing concern over what these firms perceive as a less hospitable environment to make investments and grow domestic market share. Many businesses believe they are being held to higher regulatory standards by China’s various ministries than are their Chinese competitors, a frustration that is certainly not new but seems more explicit and intense than in previous years. China’s efforts to create a consumption and service based economy, rather than simply a manufacturing one, reflect a concern on the part of the country’s leadership that absent a domestic consumer economy, China’s growth could stall, with social and political instability to follow. While perfectly reasonable fears, the government’s practices that have followed this recognition have meant domestic firms receive increasingly privileged positions over international companies.

When measured against these concerns, the GSK scandal takes on a different and more troubling light. Whatever corrupt practices GSK is ultimately found guilty of, the reality is that GSK’s domestic competitors are guilty of much more egregious behavior. Recent allegations that China’s largest domestic pharmaceutical

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<sup>9</sup> Andreas Tschirky and Lee Babiss, “Drug Discovery in China,” *AsiaBiotech*, Volume 10, Number 16, 2006, page 875-876.

distributor Sinopharm has two former executives who allegedly engaged in non-compliant behavior has been welcome news for an industry that recognizes domestic Chinese businesses operate much more in the gray area than most foreign companies do.<sup>10</sup> For the GSK crackdown to be taken seriously, and for it to have the right impact on the inefficiencies that persist in China's healthcare system, two things need to happen.

First, China's regulators need to turn their attention equally towards domestic players, and make sure multinationals see their competitors also be held accountable. Second, the reimbursement practices that lead to chronic revenue shortfalls in hospitals, and the ongoing poor pay for public hospital doctors need to be addressed. Absent either change, the only effect of the GSK scandal will be to push corrupt practices further away from companies towards distributors, independent sales representatives, and dealer networks where businesses can claim they have no directly knowledge of, or influence on, corrupt activities. While this position may satisfy the Foreign Corrupt Practices Act (FCPA), it does nothing to change the political realities within China that made the pursuit of GSK and other life science companies all but inevitable.

The NDRC is only one of three regulatory bodies in China that have AML enforcement capabilities. The other two, the Ministry of Commerce (MOFCOM) and the State Administration of Industry and Commerce (SAIC) also retain AML capabilities that impact foreign life science companies.<sup>11</sup> The NDRC's power has been challenged in the last year, largely by reformers within China who believe the ministry has become unresponsive to the need for further economic reforms. The March 2014 National People's Congress encouraged interpretations of the NDRC's diminished power, even though nothing has changed with respect to the NDRC's AML authority. In fact, the NDRC still maintains broad authority to go after businesses that it believes are engaged in activities not beneficial to the Chinese consumer. If the NDRC is further weakened relative to its ability to regulate the economy through issuing approvals and key licenses, it will most likely protect what power it still (which remains significant) has by leveraging fines on what the NDRC believes to be misbehaving companies.

For pharmaceutical and medical device companies, the NDRC's new political reality likely means the industry should anticipate more pressure from the NDRC specific to charges of anti-monopolistic pricing, a strategy that has already been used successfully this past summer to go after a number of the largest multinational

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<sup>10</sup> Patti Waldmeri, "Sinopharm executives targeted in China corruption probe," *Financial Times*, January 13, 2014, <http://www.ft.com/intl/cms/s/0/31e8a8ec-7bf4-11e3-84af-00144feabdc0.html>.

<sup>11</sup> Hao, Sue, John Lenhart, "China's 'Golden Year' of Antimonopoly Investigations," *China Business Review*, December 12, 2013, <http://www.chinabusinessreview.com/chinas-golden-year-of-antimonopoly-investigations/>.

pharmaceutical companies operating in China. Companies understandably want to gauge whether they can anticipate a NDRC investigation. Beyond a simple fight for relevancy on the part of the NDRC, what triggers the NDRC's wrath? Two factors seem to best explain when the NDRC chooses to pursue such an investigation. Neither of these factors is within the control of the private sector, a troubling realization many life science companies are coming to terms with today.

First, the NDRC's attention will be provoked if domestic consumption of a particular good outpaces domestic production of the good in question, and this good is perceived to be of national importance. In the past, for semiconductor chip production in particular, the NDRC has been used by the central government to reinforce a message to domestic industry (the government "has your back," so increase chip manufacturing capacity so we do not have to buy as much foreign product), at the same time a different message is sent to foreign companies (you have "too much" market share – if you want to keep it, figure out how to partner with a domestic counterpart). This narrative is particularly sensitive in the life science sector given China's stated objective of establishing a vibrant domestic pharmaceutical industry. Here, the threat of a new, or expansion of an old, AML case by the NDRC may carry with it the implicit understanding that the company in question has not been adequately active in the identification of Chinese R&D partnerships.

Second, the NDRC chooses to pursue an AML investigation when political pressures accrue and require some sort of response by the central government. Unfortunately, there is little doubt that China's healthcare economy has been – and will continue to be – in such a precarious situation. The potential backlash against China's government by its people over frustrations with the country's poor healthcare system continues to be an ever-present concern. One way these frustrations can be redirected away from the government is to turn them towards the private sector, of which both domestic and foreign pharmaceutical companies remain front and center. This means that the NDRC's powers are likely to continue to be directed towards life science companies (both foreign and domestic), especially given the unique role prescription costs play in the total healthcare expenditure for Chinese families.

If, either because the NDRC is fighting to retain its legitimacy, or if the central government should increasingly look to use the NDRC's powers to channel general frustrations about China's healthcare system away from it and towards the private sector, the industry will see more crackdowns such as those from last year. The bigger problem is that these crackdowns are likely to be highly volatile, disorganized, and as such difficult to predict. Foreign companies are closely watching what GSK's ultimate penalty will be. The more egregious their fine, the more likely foreigners are going to fundamentally re-evaluate their future China plans. The country's leadership understands this, and while it is not eager to drive out foreign life science companies, it has two other goals (driving costs down and fostering a domestic industry) that remain primary.

What China's policy makers – the NDRC especially - are likely to pursue will be uneven and high profile examples of behaviors that are perceived to negatively impact the consumer. At the same time, the NDRC's actions will drive further behind closed doors a discussion between the Chinese government and individual life science companies about what businesses need to bring to the table in exchange for ongoing market access. The NDRC is uniquely positioned to accomplish all of this through application of the powers it still retains. Businesses should take note of the NDRC's diminished powers, but would do well not to overlook the ways in which the NDRC's ongoing capabilities can and will be used to shape market access.

Questions of fairness – whether regulations are applied evenly to domestic versus foreign players – are not unique to the life science sector in China. Many other industries, as evidenced by surveys conducted by the US-China Business Council and the American Chamber of Commerce attest, also share these frustrations.<sup>12</sup> Similarly, the pressure to transfer technology to Chinese counterparts is not new to the life science category. However, the American life science sector encounters China and its policy goals at a different point in both parties' respective development than other sectors have enjoyed: the life science category is more dependent on China to sustain its growth and profit targets than other industries have been in the past, and China's capability to disrupt global value chains – even those that are higher technology in nature – is more sophisticated than it has ever been. In the past, higher technology industries could engage in technology transfer with their Chinese counterparts by offering less sophisticated technology; today, China expects to get the best.

It is important to recognize that China, unlike the U.S. or E.U., does not have a mature venture capital market. As such, the Chinese government acts as not only the policy agent to establish life science innovation hubs, but also as the primary funder of domestic R&D. This extends even to established Chinese pharmaceutical companies who, despite enjoying torrid growth, have been slow to make R&D investments. This means that the Chinese government is looking for incentives – both formal and informal – to encourage American collaborations with Chinese partners, regardless of the fears by U.S. companies of IP loss. American multinational life science companies understand these risks all too well, but several have been able to manage this risk while at the same time accommodating the Chinese central government's policy objectives by collaborating with Chinese Contract Research Organizations (CRO). To-date, the best example of this approach has been the partnership between the Chinese CRO WuXi Pharmatech and Bristol-Myers Squibb.<sup>13</sup>

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<sup>12</sup> "USCBC 2013 China Business Environment Survey Results," The US-China Business Council, <http://www.uschina.org/media/press/uscbc-2013-china-business-environment-survey-results>.

<sup>13</sup> "Bristol-Myers Squibb to Partner with WuXi Pharmatech," *ChinaBio*, March 7, 2011, <http://www.chinabiotoday.com/articles/20110307>.

In these relationships, the American pharmaceutical company intentionally carves up a body of bench science work that it needs to have completed, typically related to a particular component of the drug discovery process that is labor intensive and not easily automated. This may be as specific as looking at one specific part of a larger molecule and completing the science on how that part of the molecule reacts to a variety of previously defined agents. The division of this piece of work is designed such that each piece on its own is not commercially or clinically valuable. The assembly of the completed work by a variety of strategically chosen Chinese CROs then takes place back in the pharmaceutical company's domestic market. This assembly process then allows the American life science firm to have control of the most valuable piece of the research, and to have a reasonably high degree of confidence that if IP loss specific to the molecule in question does occur, it can trace back to where this was likely to have taken place.

Over the short term, this sort of R&D segmentation is likely to be an effective tactic to address IP drift. In addition, the relative immaturity of core academic and clinical infrastructure within China means that the country will continue to lag the U.S. with respect to its ability to internalize life science IP. However, China has shown itself to be remarkably adept at moving up the value chain, even into high technology sectors such as clean-tech. As such, it would be a mistake to think that R&D segmentation via CROs will be anything more than a temporary solution. Dr. Ling Su, a leading expert on China's drug development policies, points to three types of partnerships he sees taking place between domestic Chinese and overseas pharmaceutical companies: "The first is a licensing scenario. The second is a co-development scenario. The third is even more dramatic: a joint venture is set up to develop a novel medicine in China."<sup>14</sup> As China's domestic capabilities expand and become more mature, life science companies will begin to structure more joint ventures focused on unique medicine development, an important step in China's push towards having a globally viable life science sector.

Among the most important protections of American life science IP are China's patent laws, which to the Chinese government's credit, have been improving. In the U.S. Trade Representative's (USTR) *2013 Report to Congress on China's Compliance with the WTO*, several outstanding concerns related to IP issues were brought forward. Specifically, the language in Article 26.3 of China's State Intellectual Property Office (SIPO) regarding levels of disclosure by pharmaceutical companies that are more burdensome and detailed than what is required in either the American or European equivalent regulatory agency. Not only is the information more technically exhaustive than what is required for similar U.S. or E.U. filings, but also the information must be presented when the application is first turned into SIPO. Some analysts have suggested SIPO's intentions are not malicious; rather, that the agency

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<sup>14</sup> Su, Ling, "Drug Development Models in China and the Impact on Multinational Pharmaceutical Companies," *The Food and Drug Law Institute*, September/October 2013, page 22.

is in the midst of creating new law for a sector it – as a regulatory body – and the nation in general – do not fully understand. Other analysts see Article 26.3 as being intentionally designed to force technology transfer.

Regardless of SIPO's intentions relative to Article 26.3, the question of technology transfer in exchange for market access is one that is unlikely to occur within the public discourse. Rather, more companies are likely to find that among the lists of demands from the Chinese government in order for their companies to sell into the public healthcare market in China, will be the understanding that they must allocate more of their global R&D budget towards collaborations in China. These represent important, if hidden, exchanges that many life science companies feel ill prepared to counter. It is here the assistance of the U.S. government will be most important, as an agent actively seeking to protect the interests of American life science companies as they seek to navigate the China market.

### **Recommendations for Congress**

- The policy environment China is crafting for the life science sector holds many similarities to what the country did in pursuit of a globally dominant position with respect to clean-tech. To the extent American policy makers are not content to allow China to be as successfully disruptive in biotech as it has been in clean-tech, the U.S. will need to ensure that we remain the best place to conduct leading edge research in the life sciences. This prioritization should be reflected not only in government funding, but also in addressing long-standing concerns life science companies have raised about drug development costs, commercialization timelines, FDA approvals, and patent longevity.
- Elevate the Chinese government's handling of life science companies – specifically uneven application of AML standards between domestic and foreign companies – within the context of Strategic and Economic Dialogues (SE&D). Many companies have attempted to deal with technology transfer and market access issues independent of bilateral discussions between the U.S. and Chinese governments. As the pressure on price and IP increases, the SE&D forum will become a more important focal point where the life science community needs representation.
- Review the current WTO protocols to ensure they accommodate the unique needs of the life science sector. In particular, because of the predominant role China's government plays in paying for healthcare, the *WTO Government Procurement Agreement* (GPA) needs to be revisited to ensure it provides adequate coverage for the purchase of pharmaceuticals, medical devices and diagnostic equipment by China's Ministry of Health and Ministry of Finance.

- Continue pressure on China's SIPO to modify the disclosure standards within Article 26.3 to align these with international norms. Specifically, address problems created by Article 26.3 when China invalidates patents granted prior to Article 26.3's passage. Those patents that have been invalidated should be reviewed and re-established as warranted by international standards.
- Push for revision of the SIPO language specific to "new chemical entity," a poorly defined phrase that has allowed Chinese pharmaceutical manufacturers to receive approval from the CFDA before the six year period of protection China's IP laws establish. As currently defined, proprietary data provided by companies to China's regulators is not adequately protected from domestic competition.